



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

January 18, 2002

OFFICE OF
ENVIRONMENTAL INFORMATION

MEMORANDUM

SUBJECT: Peer Review of *Guidance on Assessing Quality Systems (EPA QA/G-3)*

FROM: Nancy W. Wentworth /s/ Nancy W. Wentworth
Director, Quality Staff (2811R)

TO: Peer Review Panel

Attached is the January 2002, Peer Review Draft of *Guidance on Assessing Quality Systems (EPA QA/G-3)*. This technical guidance was developed by EPA to assist those involved in assessments of quality systems to meet requirements provided in *EPA Requirements for Quality Management Plans (EPA QA/R-2)* and *EPA Manual 5360 A1* and to gain value from the process. It discusses both internal and external assessments of EPA's quality system and of the quality systems of those performing work for and with EPA. It does not address certification of quality or environmental management systems, as conferred by the International Standards Organization (ISO) or others.

This Peer Review version of the guidance incorporates significant revisions to the initial annotated outline (dated July 2000) and draft (dated January 2001), including conversion to Plain English and the addition of examples for using the graded approach.

You are asked to review all aspects of the document for relevance, usefulness, and overall adequacy as guidance for conducting and participating in assessments of quality systems. Your overall review is most appreciated, as well as your comments on the following questions:

1. Does the document begin with a clear indication of what it aims to address and how it would benefit the reader?
2. Is it clear that this is a guidance document? The document attempts to avoid being prescriptive, but rather to describe a method to assess a variety of issues depending on the nature of the quality system and its implementation status. Is this the right message, and is it communicated effectively? (We are still working with the Office of General Counsel on language to make it clear that this is guidance and provides no judicially reviewable rights.)

3. The document discusses planning the assessment activity, selecting aspects of the quality system to assess, and executing the assessment. Does it strike the right balance between them in terms of relative emphasis and level of detail?
4. Are the examples helpful in demonstrating the application of the graded approach?
5. In your experience with other types of management or related assessments that may be performed on or by an organization, does this guidance reflect practices that are expected to be encountered, and that are exemplary of best practices?
6. Overall, how useful will this guidance be for its intended audience?

Please feel free to offer comments and suggestions that go beyond this charge, as you see fit.

To meet EPA's schedule for publishing this document, it is important for us to receive your comments by March 15, 2002. Please send written comments to:

Pat Laformara
Quality Staff (MS-104)
U.S. EPA
2890 Woodbridge Avenue
Edison, NJ 08837-3679
Phone: (732) 906-6988
Fax: (732) 321-6640
E-mail: laformara.patricia@epa.gov

Thank you for your time and efforts. I look forward to your contribution.

Attachment

Guidance on Assessing Quality Systems

EPA QA/G-3

**Quality Staff
Office of Environmental Information
United States Environmental Protection Agency**

Washington, DC 20460

PEER REVIEW DRAFT

January 2002

FOREWORD

U.S. Environmental Protection Agency (EPA) policy requires all EPA organizations supporting intramural environmental programs and all non-EPA organizations performing work funded by EPA through extramural agreements to participate in an Agency-wide quality system. A quality system is the means by which an organization manages the quality aspects of its operations in a systematic, organized manner. The purpose of an assessment of a quality system is to determine the adequacy and effectiveness of the quality system being applied to environmental data operations, to report the findings to senior management, and to coordinate any necessary revision of the quality system based on the findings of the assessment.

This document provides guidance to EPA program managers and assessment teams. It does not impose legally binding requirements and may not apply to a particular situation based on the circumstances. EPA retains the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may periodically revise this guidance without public notice.

This document is one in the *U.S. Environmental Protection Agency Quality System Series* documents. These documents describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of a quality system. Questions regarding this document or others in the *Quality System Series* should be directed to the Quality Staff at:

U.S. EPA
Quality Staff (2811R)
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Phone: (202) 564-6830
Fax: (202) 565-2441
e-mail: quality@epa.gov

Copies of the EPA *Quality System Series* documents may be obtained from the Quality Staff or by downloading them from the Quality Staff Home Page:

<http://www.epa.gov/quality>

TABLE OF CONTENTS

	<u>Page</u>
CHAPTER 1. ASSESSMENTS IN THE QUALITY SYSTEM	1
1.1 QUALITY SYSTEM CONTEXT	1
1.2 ASSESSMENTS OF QUALITY SYSTEMS	3
1.3 REQUIREMENTS FOR ASSESSMENTS OF QUALITY SYSTEMS	5
1.4 INTENDED AUDIENCE	7
1.5 SUPERSESSION	7
1.6 PERIOD OF APPLICABILITY	7
1.7 ADDITIONAL REFERENCES	7
 CHAPTER 2. MANAGING ASSESSMENTS	 9
2.1 ASSESSMENT ROLES AND RESPONSIBILITIES	9
2.2 ASSESSMENT SYSTEMS	9
2.3 DECISION TO CONDUCT THE ASSESSMENT	12
2.4 CRITERIA FOR THE ASSESSMENT	12
2.5 SCOPE OF THE ASSESSMENT	13
2.6 THE ASSESSMENT TEAM	14
2.6.1 Assessment Team Selection	14
2.6.2 Assessment Team Leader Responsibilities	15
2.6.3 Assessor Responsibilities and Qualifications	15
2.7 ASSESSMENT COSTS	16
 CHAPTER 3. PREPARING FOR THE ASSESSMENT	 17
3.1 DOCUMENTATION AND TRACKING	19
3.2 ASSESSMENT TEAM PREPARATION	19
3.3 INITIAL CONTACT WITH THE ASSESSEE	20
3.4 INFORMATION REVIEW	20
3.5 ISSUE IDENTIFICATION	21
3.6 IDENTIFY INTERVIEWEES AND DOCUMENTS	23
3.7 ALTERNATIVES TO ON-SITE INTERVIEWS	26
3.8 PREPARATION OF THE ASSESSMENT PLAN	26
3.9 REVIEW AND APPROVAL OF THE ASSESSMENT PLAN	28
3.10 CONFIDENTIALITY	28
3.11 ASSESSMENT COORDINATION AND LOGISTICAL ARRANGEMENTS ..	29
3.12 FORMAL NOTIFICATION OF THE ASSESSEE	29
3.13 PREPARATION OF CHECKLISTS AND OTHER ASSESSMENT AIDS	31

	<u>Page</u>
CHAPTER 4. CONDUCTING THE ASSESSMENT	35
4.1 CONDUCT THE OPENING MEETING	36
4.2 REVIEW DOCUMENTS AND RECORDS	36
4.3 CONDUCT INTERVIEWS	37
4.4 REFERENCE RESULTS OF INFORMATION COLLECTION ACTIVITY ...	39
4.5 COMPILE PRELIMINARY FINDINGS	39
4.6 CONDUCT THE CLOSING MEETING	40
CHAPTER 5. REPORTING AND FOLLOW-UP	41
5.1 EVALUATING COLLECTED ASSESSMENT INFORMATION	41
5.2 REPORTING FINDINGS	42
5.3 CORRECTIVE ACTION AND FOLLOW-UP ACTIVITIES	43
5.4 FORMAL CLOSE OUT OF ASSESSMENT	44
5.5 QUALITY IMPROVEMENT	44
CHAPTER 6 REFERENCES AND SUPPLEMENT READING	47
6.1 REVERENCES	47
6.2 SUPPLEMENTAL READING	47
GLOSSARY	51
APPENDIX A. GUIDANCE FOR THE ASSESSEE	A-1
APPENDIX B. INTERVIEWING SKILLS	B-1
APPENDIX C. EXAMPLE ASSESSMENT ISSUES WITH INTERVIEW QUESTIONS FOR DEVELOPING AND MATURE QUALITY SYSTEMS	C-1
APPENDIX D. EXAMPLE CHECKLIST.....	D-1

LIST OF FIGURES

	<u>Page</u>
Figure 1. EPA Quality System Components and Tools	2
Figure 2. Systematic Planning Activities for an Assessment	18
Figure 3. Example Job Categories For Interviews	24
Figure 4. Example Documents and Features To Review	25
Figure 5. Example Contents of a Plan for Assessing a Quality System	27
Figure 6. Example Formal Notification Letter	30
Figure 7. Flow Chart for Conducting the Assessment	35
Figure 8. Agenda for the Opening Meeting	36
Figure 9. Agenda for the Closing Meeting	40
Figure 10. Typical Steps for Assessment Reporting and Follow-Up	41
Figure 11. Example Assessment Report Outline	42
Figure 12. Example Close-Out Letter	45

LIST OF TABLES

	<u>Page</u>
Table 1. Examples of Assessment Roles	10
Table 2. Example Row of Working Paper Matrix for Recording Assessment Observations	34
Table 3. Example of a Shell of a Corrective Action Plan	43
Table B-1. Types of Questions	B-2

(This page has been left blank intentionally.)

CHAPTER 1

ASSESSMENTS IN THE QUALITY SYSTEM

1.1 QUALITY SYSTEM CONTEXT

A quality system is a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products, and services. It provides the framework for planning, implementing, documenting, and assessing the work performed by the organization and for carrying out quality assurance (QA) and quality control (QC) activities.

Since 1979, EPA policy has required participation in an Agency-wide quality system by all EPA organizations (i.e., offices, regions, national centers, and laboratories) supporting intramural environmental programs and by non-EPA organizations performing work funded by EPA through extramural agreements. EPA's quality system operates under the authority of EPA Order 5360.1 A2 (EPA, 20001a) *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, EPA Manual 5360 A1 (EPA, 2000b) Requirements for implementing the Order in EPA organizations are given in *EPA Quality Manual for Environmental Programs*. Requirements for extramural organizations are given in 40 *Code of Federal Regulations* (CFR) 30, 31, 35, and 48 CFR 46, and *EPA Requirements for Quality Management Plans (EPA QA/R-2)* (EPA, 2001). Figure 1 illustrates EPA's quality system. All EPA QA policies and requirements documents are available at <http://www.epa.gov/quality>.

EPA bases its quality system on *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC E4-1994), which was developed by the American National Standards Institute (ANSI) and the American Society for Quality (ASQ). EPA quality system requirements are based on these specifications, so it is not necessary to consult the ANSI/ASQC specifications to comply with EPA requirements. Extramural quality systems that demonstrate compliance with the ANSI/ASQC specifications for quality systems are also in compliance with EPA policy.¹

Every EPA organization or extramural organization performing work funded by EPA is required to document its quality system in an approved Quality Management Plan (QMP) (through internal Agency orders or Federal regulations listed above). The quality of environmental data is known when all steps associated with its generation are documented and when such documentation is verifiable and

¹Chapter 6, References and Supplemental Reading, list documents from ASQ and the International Organization for Standardization (ISO), which may be helpful to the reader.

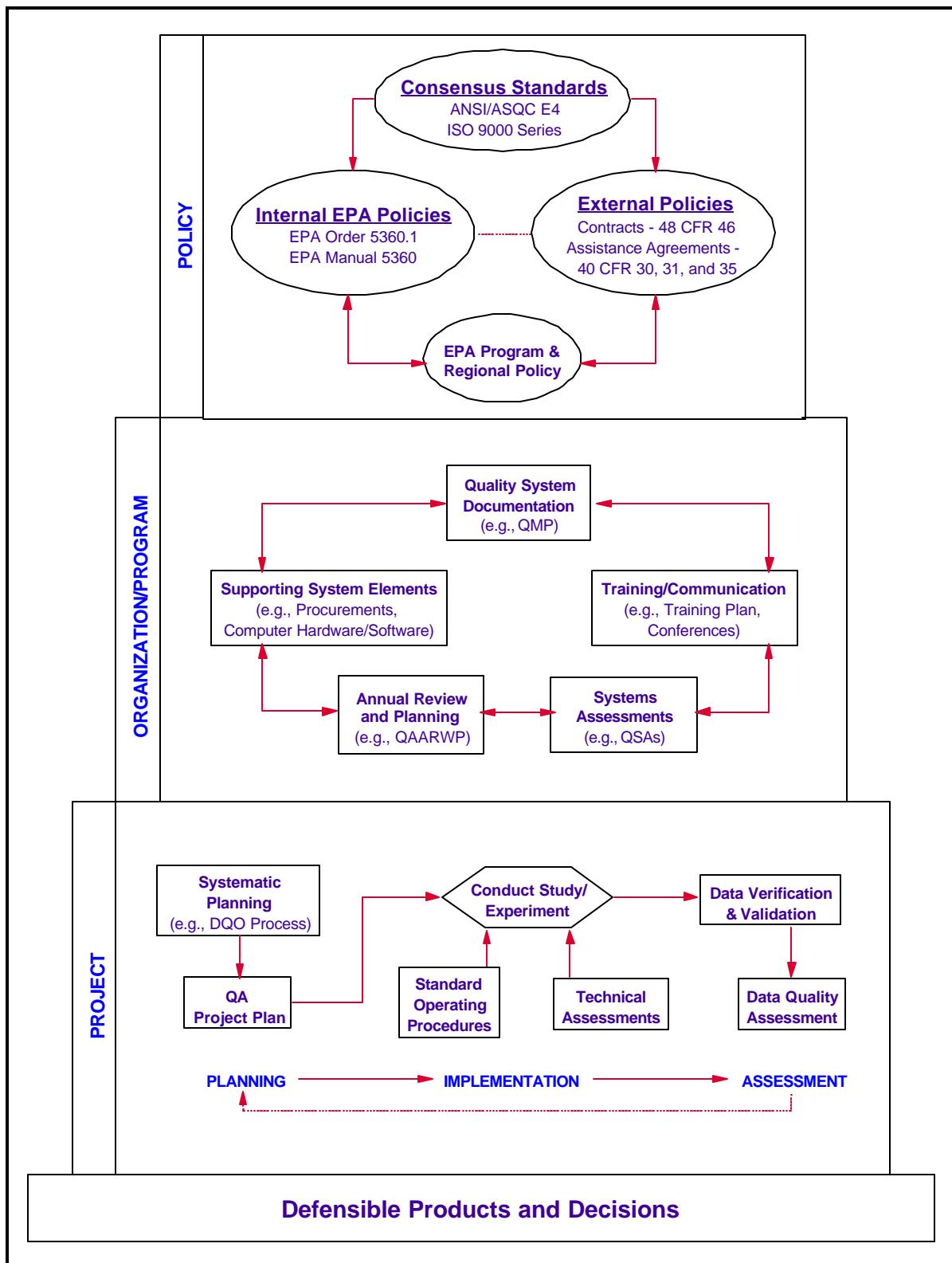


Figure 1. EPA Quality System Components and Tools

defensible. Because Agency decisions rely on the quality of environmental data, it is imperative that the effectiveness of the quality systems that support the collection and use of environmental data be periodically assessed.

Section 7.a(3) of the EPA Order 5360.1 A2 requires the Agency Senior Management Official for Quality to perform periodic management assessments of all EPA organizations, and Section 6.a(4) requires EPA organizations to perform assessments of the effectiveness of their quality system at least annually. EPA regulations governing extramural agreements addressed in 48 CFR 46 and 40 CFR 30, 31, and 35 require the assessment of extramural organizations by EPA.

Extramural organizations, which include financial assistance agreement recipients, cooperative agreement recipients, contractors, and grantees (States, tribal governments, Local governments, universities, contractors, etc.), are also required to conduct periodic internal assessments of their own quality systems. An extramural organization's assessment process is described in its Quality Management Plan. Additionally, assessments play an important role in the continuous improvement process.

EPA Quality Management Plan requirements apply to grants and enforcement agreements, decrees, and orders. For enforcement agreements, the authority to assess is not guaranteed unless it is included in an order or decree or is specified by statute.

1.2 ASSESSMENTS OF QUALITY SYSTEMS

An assessment of a quality system is a systematic, independent, and documented examination that uses specified assessment criteria to answer one or more of the following questions about an organization's quality system:

- If an organization is developing a quality system, what QA activities remain to be implemented and what technical assistance by the assessors will promote the development and implementation of this quality system?
- Is the organization's quality system documented and fully implemented?
- Does the organization understand external quality requirements?
- Does the quality system comply with external quality requirements?
- Do the activities that are being performed by the organization comply with its quality system documentation, particularly the Quality Management Plan?
- Are the quality system procedures implemented effectively?
- Does the quality system support environmental decision making with processes that ensure that data are sufficient in quantity and quality appropriate for their intended purpose?

An assessment is designed to provide objective feedback about the quality system. It evaluates and documents the management policies and procedures that are used to plan, implement, assess, and correct the technical activities for environmental programs. It includes quality system document review, file examination and review, and interviews of managers and staff responsible for environmental data operations. Assessments can be conducted for specific environmental programs within organizations. Assessments can apply to entire organizations, suborganizational units, and one or more environmental programs.

This guidance addresses assessments of quality systems at the organization level that focus on process rather than the quality of data from specific projects. Depending upon which of the previous questions are addressed and local usage of terms, these assessments also have been referred to as quality system audits (QSAs), management assessments, and management systems reviews (MSRs) or management system audits (MSAs). For example, the term MSR is used to describe an assessment of a developing quality system. MSRs may include providing technical assistance for developing and implementing a quality system as an assessment objective.

One purpose of assessments is to improve the quality system, whether it is mature or developing. To accomplish this purpose, the objectives of an assessment need to be appropriate to the current developmental stage of the quality system. For a developing quality system, the objectives may be to perform a gap analysis of the quality system and to advise the assessee about any components of the quality system for which more support and training are needed. For a mature quality system, the objective may be to determine whether the quality system is effective as implemented. Systematic planning is needed to ensure that an assessment's objectives are appropriate.

Another purpose of assessments is to provide valid feedback to management on the adequacy, implementation, and effectiveness of the quality system. Assessments are helpful because the process emphasizes noting good practices and suggesting changes for improving the quality system that provides data for defensible environmental decisions.

In addition, the overall assessment program is beneficial to the Agency-wide quality system. Assessors are in a good position to gather information on the reasonableness of the quality requirements and the consistency of their implementation across all organizations and programs. Assessments could indicate that additional quality policies and procedures, guidance documents, etc., need to be developed and implemented, or that additional training needs to be developed and provided. If assessments find that specific management and technical practices do not aid in environmental decision making, such findings could lead to modifications of these practices. Assessments of quality systems will benefit the Agency in general by providing increased confidence in environmental decisions and strengthening its overall credibility.

Although the assessments share many aspects with environmental management systems audits and quality audits that are performed under independent certification authorities such as the International Standards Organization, they are not necessarily equivalent. A certification audit does provide an acceptable substitute for the assessment of a quality system where the Agency recognizes the adequacy of the consensus standards, but it is by definition limited to the purpose of compliance to the standardized criteria of the consensus standard. Note that certifications audits are performed by an outside organization for a fee. The assessments discussed here are performed primarily by those who work for the authority who has the ultimate responsibility for the quality system being assessed or the authority that is funding the work being done by the assessed quality system. In this respect, the assessments more closely resemble self-certification audits.

1.3 REQUIREMENTS FOR ASSESSMENTS OF QUALITY SYSTEMS

An organization's Quality Management Plan spells out roles and responsibilities for implementing assessments, as well as the uses of assessment types in the organization. EPA Manual 5360 A1 requires Quality Management Plans to discuss or address the following items pertaining to management and technical assessments:

- how the process for planning, scheduling, and implementation of assessments works and how the organization will respond to needed changes
- the responsibilities, levels of participation, and authority for all management and staff participating in the assessment process
- how, when, and by whom actions will be taken in response to findings of assessments and how the effectiveness of the response will be determined.

Furthermore, EPA's requirements for Quality Management Plans specify that the plans describe or reference the processes (i.e., roles, responsibilities, and authorities) of management and staff for:

- assessing the adequacy of the quality system at least annually
- planning, implementing, and documenting assessments and reporting findings to management including how to select assessment tools, the expected frequency of their application, and the roles and responsibilities of assessors
- determining the level of competence, experience, and training necessary to ensure that personnel conducting assessments are technically knowledgeable, with no real or

- 131 perceived conflict of interest, and have no direct involvement or responsibility for the
132 work being assessed
- 133 • ensuring that personnel conducting assessments have sufficient authority and access to
134 programs, managers, documents, and records, and organizational freedom to:
- 135 - identify both quality problems and noteworthy practices
136 - propose recommendations for resolving quality problems
137 - independently confirm implementation and effectiveness of solutions
- 138 • having management review and respond to findings
- 139 • identifying how and when corrective actions are to be taken in response to assessment
140 findings, ensuring that corrective actions are made promptly, confirming the
141 implementation and effectiveness of any corrective action, and documenting such
142 actions that include:
- 143 - identifying root causes
144 - determining whether the problem is unique or has more generic implications
145 - recommending procedures to prevent recurrence
- 146 • addressing any disputes encountered as a result of assessments.

147 According to the ANSI/ASQC specifications for quality systems, assessments of environmental
148 programs will be conducted periodically and the assessment findings will be evaluated to measure the
149 effectiveness of the programs' quality systems. The types of assessments that can be conducted include
150 management self-assessments, management independent assessments, technical self-assessments, and
151 technical independent assessments. The specific type of assessment that is used is determined by
152 management.

153 The EPA quality system is characterized by the principle of the "graded approach," which
154 allows QA Managers to base the level of quality assurance and quality control applied to an
155 organizational area or project on the intended use of the environmental program and on the confidence
156 that is needed and expected in the quality of the program. The graded approach is also used in
157 developing an assessment strategy that is appropriate for both the organization that performs the
158 assessments and the quality system that is assessed. This approach starts with systematic assessment
159 planning and continues through the assessment's implementation and reporting phases. The graded
160 approach is used to guide assessment planning decisions and to guide the collection of desired
161 information about the quality system being assessed.

The graded approach is an important consideration in determining the scope and frequency of assessments. For example, a water quality monitoring project with limited scope and complexity may require less frequent and less complex assessments than will a multi-program environmental performance partnership agreement (EnPPA) with a state. Organizations that are responsible for highly visible enforcement activities may require more extensive assessments than organizations that perform basic research. Assessments of small organizations may be less extensive than assessments of large organizations.

1.4 INTENDED AUDIENCE

This document is intended for all EPA and extramural organizations that have quality systems based on EPA policies and requirements and that may need to periodically assess these quality systems for compliance to the requirements. It is also intended for organizations whose quality systems are assessed by EPA. In addition, this guidance may be used by other organizations needing to assess quality systems applied to specific environmental programs.

1.5 SUPERSESSION

This document discusses a component of the EPA quality system for which guidance has not been previously issued. *Guidance for Preparing, Conducting, and Reporting the Results of Management Systems Reviews* (EPA QA/G-3, draft #2, January 1994) was prepared, but that document was never finalized.

1.6 PERIOD OF APPLICABILITY

Consistent with requirements set forth in EPA Manual 5360 A1, this document will be valid for 5 years from the official date of its publication. After 5 years, this document will either be reissued without change, revised, or withdrawn.

1.7 ADDITIONAL REFERENCES

Other documents are available to provide guidance for developing suitable and effective quality systems for environmental programs. They establish criteria and mandatory specifications for QA and QC activities and provide guidance for documenting various components of a quality system, such as technical systems audits, standard operating procedures (SOPs), and QA Project Plans. A list of these documents is provided in Chapter 6, References and Supplemental Reading. Since they contain guidance for activities critical to successful environmental data collection activities and operations, they serve as important resources for planning and conducting assessments.

CHAPTER 2

MANAGING ASSESSMENTS

2.1 ASSESSMENT ROLES AND RESPONSIBILITIES

The authorizing entity for an assessment is whoever authorizes the assessment and has the authority to do so. The authorizing entity for an assessment can be the individual ultimately responsible for the quality system that is being assessed. For instance, for internal assessments performed by an EPA Regional Office, the authorizing entity is the Regional Administrator. The authorizing entity is given the opportunity to approve the assessment plan, receives the assessment findings, may need to mediate any disputes, and may monitor responses to and implementation of any corrective actions.

The assessee is the organization being assessed, and an assessor is a person who performs the assessment. An assessor can be an individual either from part of the organization being assessed (i.e., an internal assessment) or from an outside organization (i.e., an external assessment). For external assessments, the assessors are independent of the assessed organization. For internal assessments, the assessors are not directly involved in performing or managing the environmental program. Table 1 gives examples of the roles that various organizations may play in internal and external assessments.

2.2 ASSESSMENT SYSTEMS

Organizations that conduct multiple assessments may establish a system to ensure that assessments are performed consistently and according to current quality requirements (see Worthington, 1998). The assessment system will focus on planning and establishing priorities for assessments, assessment frequency, scheduling, conducting assessments, procedures and formats for assessment reports, and assessor qualifications and training. SOPs are developed that describe the assessment procedures in sufficient detail to encourage consistency in how assessments are performed.

Effective assessment systems answer four key questions for assessment system managers:

1. Am I doing the right job? (Do I select those assessments that will make a significant contribution to the overall quality system?)
2. Am I doing the job right? (Does the assessment system use its personnel and resources efficiently?)
3. Am I getting the desired results? (Do the assessments have a beneficial effect on the assessed quality systems?)

4. Does my organization consistently do high-quality work? (Is care taken in the selection, planning, performance, reporting, and follow-up of assessments? Are assessment findings given a final quality check before they are sent out?)

Table 1. Examples of Assessment Roles

Assessments of	Assessee	Authorizing Entity	Assessors
EPA organization	Program/Regional Office/Laboratory (external assessment)	Assistant Administrator, Office of Environmental Information (OEI)	OEI Quality Staff and technical experts as needed
	Program/Regional Office/Laboratory (internal assessment)	Assistant/Regional Administrator	Program/Regional Office staff and technical experts as needed
Assistance agreement recipient/ contractor	State or tribal environmental agency, nonprofit organization, or other assistance agreement recipient/contractor (external assessment)	EPA Program/Regional Office, Laboratory, or Division Director	EPA program office, laboratory, or division QA staff and technical experts as needed
	State or tribal environmental agency, nonprofit organization, or other assistance agreement recipient/contractor (internal assessment)	Director of State or tribal environmental agency, nonprofit organization, or other assistance agreement recipient/contractor	Staff of State or tribal environmental agency, nonprofit organization, or other assistance agreement recipient/contractor and technical experts as needed

A graded approach is factored into designing an appropriate assessment system. Some organizations may not have adequate staffing to follow all of the steps outlined below, but all organizations are encouraged to consider these topics and to implement them within their assessment system when possible and appropriate.

Managers of an assessment system, who provide administrative support to the assessors, have practical knowledge of assessment procedures and practices. These individuals:

- 239 • are independent of direct responsibility for implementing the projects being assessed
- 240 • clarify the authority to assess within the organization, if necessary
- 241 • establish awareness of the assessment system by potential users and potential assessees
- 242 • emphasize the benefits of a well-established and functional quality system
- 243 • establish priorities for quality systems to be assessed
- 244 • ensure that adequate resources are available for the assessment system
- 245 • establish an assessment QC system
- 246 • evaluate assessor training needs regularly and provide appropriate training opportunities
- 247 • ensure that procedures are in place for planning, scheduling, conducting, reporting, and
- 248 following up on assessments, and that assessments are consistently documented
- 249 • select assessment team leaders, approve assessment teams, and ensure that they
- 250 receive administrative support
- 251 • review assessment findings
- 252 • resolve any disputes between assessors and assessees concerning assessment findings
- 253 • transmit assessment findings to authorizing entities
- 254 • brief senior management on the status of the assessment system
- 255 • ensure that the experience gained by assessors improves the assessment system and the
- 256 quality system.

257 Management of the assessment system may be a shared responsibility performed by a small
258 staff instead of one individual. Management of the assessment system is typically not a staff member's
259 sole responsibility. For instance, the manager for assessments that are conducted by an EPA Regional
260 Office may be the Regional QA Manager.

261 An assessment QC system helps to ensure that assessments are effective and that assessments
262 of similar organizations under similar conditions by different assessment teams arrive at similar findings.
263 An assessment organization's reputation for performing high-quality assessments increases the impact of
264 their findings and the likelihood that corrective actions will be implemented.

265 The assessment system's managers create the expectation for high-quality assessments,
266 establish the policies and procedures that will produce high-quality assessments, and determine whether
267 the assessment QC system has improved the quality system. They develop procedures and criteria to
268 compare assessor performance to achieve consistency among assessors to the extent possible and they
269 regularly evaluate assessor performance. Such procedures can include assessor training workshops,
270 reviews of assessment reports, performance appraisals, and rotation of assessors among different
271 assessment teams.

272 Assessment system managers not only review findings of individual assessments, but they also
273 review the findings in a holistic way. This review process feeds back into planning with an emphasis on
274 improving both the assessment system and the quality system. For most organizations, assessments are

not just one-time events but are done on a recurring basis with assessments conducted on different groups and at different locations within the organization. The review may also identify relevant and emerging quality issues in assessments, perhaps coming from a synthesis of findings from assessments of multiple organizations. For instance, such a review may reveal areas in a quality system that are prone to problems or areas that need more controls or more training.

The graded approach is also factored into the assessment QC system. In small organizations, a fully developed QC system for the assessment process may not be possible because of limited staffing. These organizations still can incorporate aspects of a mature assessment QC system into their own system, within their constraints, to ensure the quality of their assessments.

2.3 DECISION TO CONDUCT THE ASSESSMENT

The decision to conduct the assessment usually will be made by the assessment system managers in response to a direct request from the authorizing entity or according to a schedule that has been approved previously by the authorizing entity. The decision process typically includes the identification of some or all of the following items:

- the organization to be assessed
- the authority to conduct the assessment
- the criteria for the assessment
- the scope of the assessment
- the resources available for the assessment
- the size of the assessment team
- an approximate date for the assessment
- the assessor qualifications needed to conduct the assessment
- availability of qualified assessors to conduct the assessment
- selection of the assessment team leader
- selection of assessment team members.

The assessment team leader addresses any of the above items that have not been decided by the authorizing entity or the assessment system managers.

2.4 CRITERIA FOR THE ASSESSMENT

For the assessment team to assess the adequacy and effectiveness of a quality system in an objective manner, the quality system's characteristics are compared to objective and written reference standards rather than to the subjective, unwritten expectations of the assessors or other individuals. These assessment criteria are: (1) the external policies, procedures, and requirements that are applicable to the assessee and (2) the assessee's internal policies, procedures, requirements, and

quality system planning documents. Specific criteria for quality systems of EPA organizations and of extramural organizations performing work funded by EPA through extramural agreements, enforcement agreements, decrees, or orders may include the following:

- Order 5360.1
- EPA's Quality Manual
- EPA requirements for Quality Management Plans
- ANSI/ASQC specifications for quality systems
- the assessee's Quality Management Plan
- the assessee's reports [e.g., quarterly progress reports or QA Annual Report and Work Plan (QAARWP)]
- QA and QC requirements in regulations.

It is important that the authorizing entity, the assessment team, and the assessee all agree on the assessment criteria prior to the assessment. If the parties involved in the assessment do not have a common understanding of the criteria beforehand, questions concerning the basis for the subsequent assessment findings may arise. The credibility of the assessment can be diminished if team members apply inconsistent or subjective assessment criteria.

2.5 SCOPE OF THE ASSESSMENT

The scope of the assessment may be set by the authorizing entity or it may be systematically developed by the assessment team. The scope can delimit the time period and subject matter or organizational "boundaries," and can be affected by assessor time and resource constraints. It may also include more specific items, such as the job positions of the people to be interviewed and what parts of the quality system to examine. Selection of the items may be based on their importance to the overall quality system or on concern that there might be a problem. Issues for consideration in the assessment may derive from any part of the quality system (e.g., policy, processes or procedures, products, or resources). Issues may also be derived from the findings of previous assessments. Section 3.5 contains more information about issue identification.

The scope for assessing a mature quality system will generally differ from that for assessing a developing quality system. For example, a developing quality system might not have an approved Quality Management Plan in place to serve as a basis for the assessment and is less likely to have formal QA tracking systems. For an assessment of a developing quality system, the scope may include assisting with the development of specific parts of the quality system.

The scope can be limited by assessment resource constraints, which often preclude assessing the whole quality system, so specific items are selected for inclusion in the assessment. The use of the graded approach helps to ensure that assessment resources are used effectively and efficiently where

they are needed most. Because an assessment is closely linked to the assessee's Quality Management Plan, the scope of an assessment can be estimated, to a first approximation, by the complexity and detail of the quality system described in the plan.

The scope can also be limited by what can be accomplished on-site. Planning and scheduling interviews and document reviews should consider both what can realistically be covered within the allocated resources and what needs to be covered to adequately characterize the assessed system. After the duration of the on-site portion of the assessment has been decided, the number of interviews that can be conducted during the assessment can be estimated. The time necessary for the opening and closing meetings, document reviews, and breaks is taken into account. Perhaps only six or seven one-hour interviews can be conducted per day. As is discussed in Section 2.6.1, one or two assessors should conduct each interview.

The authorizing entity approves the assessment plan and by doing so approves the scope of the assessment. However, the assessment team leader is usually enabled to modify the scope during the assessment if any relevant, but unforeseen, quality issues are encountered during the assessment. For instance, it may be necessary to interview staff members who were not identified in the assessment plan. Section 3.8 contains more information about the assessment plan.

2.6 THE ASSESSMENT TEAM

2.6.1 Assessment Team Selection

The scope of the assessment determines the size and composition of the assessment team. The scope of the assessment is determined before the assessment team members are selected. The assessors, taken as a team, need subject matter knowledge and assessment knowledge and experience. They need to be free of any real, potential, or perceived conflicts of interest. Training in the assessment process and in listening and interviewing skills is usually made available to the assessors and is usually a prerequisite for performing the assessment. Section 2.6.3 describes the assessment team qualifications in greater detail. Interviewing skills are addressed in Appendix B.

There are good reasons for an assessment team to consist of two or more members (a team leader and at least one additional assessor) (Adams, 2000). In some cases, the assessment team may need to include additional assessors as well as technical experts. For example, an internal assessment of an EPA Regional Office may be performed by an assessment team composed of a leader, two assessors, and a technical consultant with expertise in Regional Office QA programs.

During interviews, two assessors can corroborate an interviewee's responses. The use of two interviewers helps to ensure that the statements by the interviewees are recorded accurately. If there is any confusion about what was said in an interview, the two interviewers can discuss the response and

come to agreement on what the interviewee said. One interviewer may recognize an important piece of information that the other interviewer may have overlooked. This two-assessor approach can allow for “tag team” questioning. That is, while one assessor asks a question and records the interviewee’s response, another assessor can be preparing to ask the next question. Other advantages of having more than one person perform an assessment include: complementary expertise and work experience, the ability to work simultaneously with different interviewees, and cost savings in both the planning and implementation phases of the assessment.

Assessors from other organizations may be a possible resource. Permission for their participation should be obtained from their management. For assessments of EPA organizations, they are usually QA professionals for a different Regional Office, Program Office, or National Laboratory. For assessments of State agencies, a QA Manager from another State in the Region could participate in the assessment.

2.6.2 Assessment Team Leader Responsibilities

Once the need, authority, and funding for an assessment have been established, an assessment team leader and other assessment team members are selected. The assessment team leader is responsible for all phases of the assessment. The assessment team leader has management experience and ability and has the authority to make decisions during the assessment and while presenting any assessment findings. The assessment team leader also:

- may assist in selecting other assessment team members
- prepares the assessment plan and submits it for review and approval
- represents the assessment team to the assessee’s management
- manages the assessment team during the assessment
- submits the assessment report
- organizes the response to comments.

2.6.3 Assessor Responsibilities and Qualifications

According to the ANSI/ASQC specifications for quality systems, personnel conducting assessments of quality systems have the authority, access, and independence to:

- identify and report problems that affect quality
- identify and cite noteworthy practices
- if requested, propose recommendations for correcting problems that affect quality
- independently confirm implementation and effectiveness of corrective actions
- if requested, monitor the work and report to management until the identified problems have been corrected

- provide documented assurance to management that further work performed by the organization is monitored until identified problems are corrected.

Corrective actions are more likely to be initiated in response to assessment findings if the assessment team is perceived to be competent and credible. The team members have the following qualifications, which establish their competency and credibility; specifically they:

- are free from personal and external barriers to independence, organizationally independent, and able to maintain an independent attitude and appearance
- possess integrity and report only what is observed
- collectively possess adequate assessment proficiency and appropriate technical background
 - are qualified to perform their duties by virtue of education, training, and/or experience
 - understand assessment techniques and quality system concepts and principles
 - have experience appropriate for their duties in the team (leading, for example)
- understand their roles and responsibilities in the assessment process and are responsive to the assessment team leader's directions
- are familiar with the assessee's organization and with applicable regulations
- have good information-gathering and communication skills, i.e., are able to assimilate information, formulate pertinent questions, present questions clearly during interviews, listen carefully to the information being provided, and verify the information from documentation
- are even-tempered and keep potentially confrontational circumstances under control
- are organized and able to prepare assessment reports promptly.

2.7 ASSESSMENT COSTS

Knowledge of the costs of assessments helps to ensure that adequate resources can be made available. The budget for an assessment depends on the scope, objectives, duration, and complexity of the assessment. Costs are affected by the number of assessors needed, and their associated labor, travel, and lodging costs. Assessors need time to prepare for the assessment, conduct the assessment, generate the report, and if specified, verify corrective actions. Off-site activities, such as preparation and reporting, may require more time than the on-site portion of the assessment.

CHAPTER 3

PREPARING FOR THE ASSESSMENT

Planning is the most crucial part of the assessment process and a systematic approach is recommended. Chapter 2 identified initial planning activities: deciding to conduct the assessment (Section 2.3); identifying the criteria for the assessment (Section 2.4); determining the scope of the assessment (Section 2.5); selecting an assessment team to conduct the effort (Section 2.6); and allocating resources for the assessment (Section 2.7). Once these activities have been performed, the planning process can proceed to identify:

- specific information that is needed from the assessee to identify assessment issues
- specific issues about the quality system to be checked during the assessment
- the sources, quality, type, and quantity of information to be collected
- how collected information will be evaluated to determine if the quality system meets the requirements of the assessment criteria.

One major product of this process is a written plan that summarizes what will be done in the assessment. It is prepared by the assessment team and approved by the authorizing entity before being sent to the assessee prior to the assessment. Another major product is a written assessment checklist that is used by the assessment team to organize the interviews and to document the information that they will collect. Logistical arrangements for the assessment are made as part of the planning process.

Planning is just as important when assessing the need for additional support for a developing quality system (e.g., for a management systems review) as it is when assessing a fully implemented quality system (e.g., for a complex criteria-driven assessment). The implementation status and the need for additional support are determined when assessing a developing quality system, and the assessment scope and issues are designed with this quality system in mind. Regardless of the status of a quality system's development, it is important that the assessment be planned and conducted in an objective and systematic way.

In this chapter, planning activities are presented in a particular order. This does not mean that the activities must be performed in this order. Many of the activities can occur concurrently or iteratively, and the order of the activities will vary for different assessments and for different assessing organizations. For example, selecting the assessment team leader and assessment team may be the first step on some assessments, if the organization knows which staff members are the best matched technically for a particular assessment. In other instances, an assessment team leader may be selected who will then begin the initial planning and scoping, which will be followed by selection of other members of the assessment team.

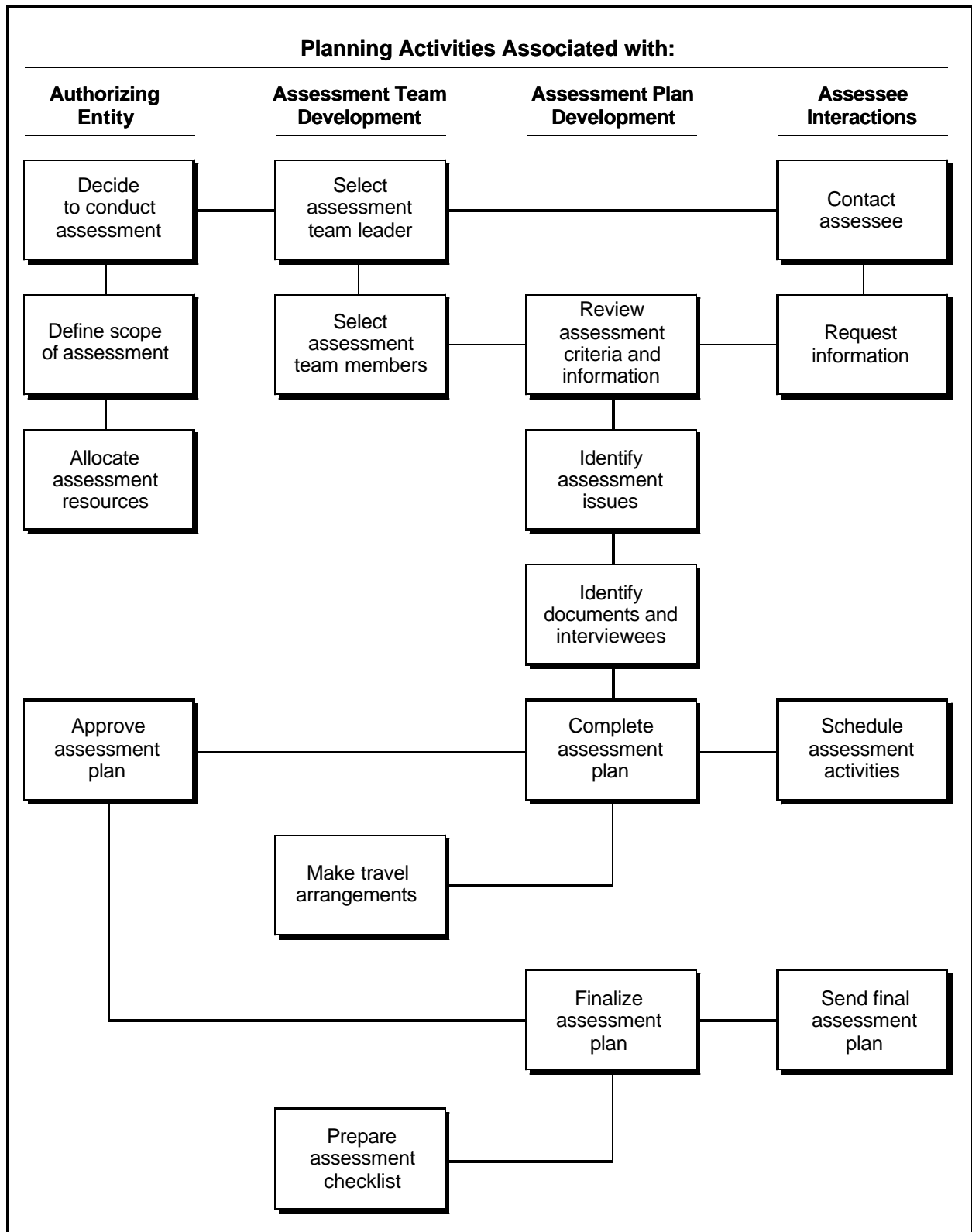


Figure 2. Systematic Planning Activities for an Assessment

Figure 2 illustrates an approach for planning activities for an assessment. This figure is not to be considered a chronological flowchart for assessment planning. The four columns in the figure correspond to four general types of activities that are associated with assessment planning. The activities in this systematic planning process are described in more detail in the rest of this chapter. The lines between the boxes show some of the logical connections between the activities, rather than a strict chronological order.

An organization may choose a different systematic planning process or may limit some of these activities as a result of applying the graded approach. For example, a quality system that is still being developed may not yet have many quality documents to be reviewed and systematic planning for this activity may not be needed. However, systematic planning is needed for any assessment, regardless of the size or complexity of the quality system being assessed. A written plan is useful for any assessment as a way to document the assessment planning, including determining the criteria for and the scope of the assessment.

3.1 DOCUMENTATION AND TRACKING

At the beginning of the planning phase, it is helpful to establish an assessment file, which helps to track the paperwork from initiation of the assessment through completion. The file may contain all materials collected before, during, and after the assessment including:

- planning documents, such as the assessment plan and the agenda
- all relevant correspondence, such as notification letters
- working papers, such as assessment checklists that record the observations from interviews and document review
- all assessment reports
- any other documents collected or arising from the assessment such as corrective action reports.

The assessment file serves to document the course of the assessment and its outcome. As the file is prepared, note that it may be possible for the public to obtain assessment files and working papers through the Freedom of Information Act. Electronic tracking of assessments may be possible in some organizations. Close-out of the assessment is often tracked or documented with a formal close-out memorandum or some other type of record.

3.2 ASSESSMENT TEAM PREPARATION

Before the on-site part of the assessment, the assessment team usually reviews information about the quality system, plans the assessment, divides up responsibility for interviews and document reviews, works out scheduling and logistical issues, and understands the requirements for note taking,

reporting, and follow up. The roles and responsibilities of individual team members are discussed. The team members' expectations for the assessment are discussed and harmonized. Assessor responsibilities and qualifications are described in Section 2.6.3.

3.3 INITIAL CONTACT WITH THE ASSESSEE

During initial contact with the assessee, the assessment team leader relays the authorizing entity's decision to conduct an assessment. The leader may make contact by telephone, e-mail, or letter with the assessee's QA Manager. The authorizing entity may have previously informed the assessee of this decision. The leader and the manager discuss possible dates for the assessment, the assessment criteria, the scope of the assessment, requests for supporting documents, and potential interviewees who are representative of the of the program areas to be assessed. The manager usually arranges for a meeting space for interviews and document reviews, ensures that requested documents will be available to the assessment team, arranges interviewee participation and logistics for the assessment, and coordinates the on-site activities with the leader. Interviews and document reviews are best conducted in a quiet place, away from potential interruptions in offices and laboratories.

The formality of the initial contact with the assessee and subsequent contacts will be determined largely by the organizational relationship between the assessors and the assessee. External assessments tend toward more formality than internal assessments. After an initial verbal contact, it may be appropriate for the assessment team leader or the authorizing entity to send a written notification of the upcoming assessment to the assessee's QA manager. Regardless of how the initial contact is made, the assessee's senior management is made aware that an assessment will be occurring.

The assessment team leader makes every effort to gain the cooperation of the assessee's senior management and its QA Manager. The process of establishing a cooperative relationship for the assessment begins with the initial contact. If the senior management and the QA Manager understand that the upcoming assessment offers an opportunity to improve their quality system, their attitude will be communicated to the rest of the organization, and the assessment can proceed more smoothly. A positive purpose will encourage the organization to implement any corrective actions that are needed to respond to assessment findings.

3.4 INFORMATION REVIEW

The review of information about the assessee's quality system establishes the knowledge base for the assessment. It is essential that the assessment team understands what is already documented about the assessee's quality system and its environmental programs in order to formulate relevant questions for the interviews and to identify pertinent case studies, documents, or reports to be examined.

Helpful information includes the requirements for the assessee's quality system and supporting documentation, such as the Quality Management Plan; applicable regulations for environmental programs; reports of previous assessments of this organization; the QA Annual Report and Work Plan (a document required by EPA Order 5360.1 A2 for EPA groups); and fiscal reports such as Government Performance and Results Act reports (for Federal groups). If these documents are not already on hand, the assessment team leader requests them during the initial contact with the assessee. Organizations with developing quality systems will generally have less documentation available for review than those with fully implemented quality systems.

Reviewing these documents will allow the assessment team to consider some or all of the following items, as appropriate for the scope of the assessment:

- the mission and quality policy of the organization
- the requirements for the quality system that are specified in the assessment criteria
- the specific roles, authorities, and responsibilities of management and staff with respect to QA and QC activities
- the means by which effective communication within the organization are assured
- the processes used to plan, implement, and assess the work performed
- the process by which measures of effectiveness of QA and QC activities will be established and how frequently effectiveness will be measured
- the level of improvement based on lessons learned from previous experience
- fiscal reports.

The assessee's fiscal reports can provide a window into the quality system because they show how money was budgeted and spent, which may be an indication of which issues are considered most important by the organization.

3.5 ISSUE IDENTIFICATION

If the authorizing entity does not prescribe the assessment issues, the assessment team identifies them and documents them in the assessment plan. Time and resources can limit an assessment, making it impossible to evaluate and characterize all aspects of a quality system. If such limitations do exist, then the assessment team has the opportunity during planning to select the specific quality system components and associated issues that will be investigated. Although the issues may be selected at random, priorities can be established using input from three sources:

- the quality system and associated (e.g., contract) requirements
- documentation about the assessee
- possible knowledge of or experience with similar organizations.

Some requirements may become assessment issues because:

- they have a significant effect on the quality of the environmental data being collected to support decision making
- they are not easy to implement or fulfill
- they are vague and contradictory or onerous and burdensome
- they are new or have been revised since the last update of the Quality Management Plan.

Documentation of quality system processes and their effect on end product development may lead to the selection of assessment issues if the products are of special importance. For example, they may be used directly for making rules, regulations, or policy or have significant national or Congressional visibility. Although the products themselves are not assessment issues, the effect of the processes used to develop them are important because they demonstrate the ability of the quality system to support rule-making and regulation and policy development.

The reports of previous assessments of the assessee may indicate quality system components that have had problems in the past and for which corrective action may have been necessary. The assessment team may decide to determine whether the corrective actions were implemented and effective. In similar fashion, the reports of assessments of other organizations may point to quality system components with common weaknesses, which may also be present in the organization being assessed. The assessment team may look for similar weaknesses in the organization being assessed.

One technique for identifying issues is to look at the completeness and clarity of written descriptions of the organization's quality system. If the assessment criteria and supporting documentation appear to describe a generic quality system, it may be necessary for the assessors to obtain more information about the quality system as implemented in this organization. If the documentation does not describe all of the specific components of the quality system and the requirements for them, the missing components or requirements may become issues. Although a thorough and lucid description of a quality system component does not guarantee that this component is being implemented or that it is effective as implemented, the lack of such a description may point to an area that merits observation during the assessment.

Assessment issues may also be identified using the information to trace or reconstruct the quality system processes affecting a program or activity from its antecedents (e.g., regulatory requirements) to its end products. A program can also be traced through the personnel who plan, implement, and assess it. If the documentation does not reveal the connection between antecedents and products, the personnel pathway, or the quality-related steps, then the assessment team may wish to allocate time during the assessment to investigate them.

A final consideration is whether the issues can be assessed for the benefit of the organization's quality system. Some issues exist due to circumstances that are not likely to be affected positively by the assessment. If that is the case, then addressing resolvable issues is preferable. Possible examples of assessment issues that may not be good choices to include in an assessment of the status of quality system implementation are:

- an organization does not have adequate oversight of assistance recipients because there is no money in the travel budget (the root cause is the travel budget, rather than implementation of the quality system)
- an organization has no access to a statistician because of a hiring freeze
- a program has not been implemented because a policy decision was not made.

3.6 IDENTIFY INTERVIEWEES AND DOCUMENTS

After the major assessment issues have been identified, the next step is to select an information collection tool that is appropriate to investigate the assessment issues. The underlying concept is that the tool enables the assessment team to understand a quality system and quickly integrate the collected information. The tool allows the assessment team to document objective evidence or observations about the quality system. Even when assessing a developing quality system, the information collection tool is still systematic and geared towards collecting objective evidence.

Generally, face-to-face interviews and document reviews are the preferred tools for collecting information in assessments because interaction with the interviewee provides the assessment team with direct information about the quality system. Supporting documentation can be consulted and questions can be explained and clarified as necessary.

There is a benefit-risk consideration associated with the use of interviews. People can be a valuable source of information in the right circumstances. However, the human mind is a very complex and vulnerable observation instrument. If the assessment team does not ask the right people the right questions, they may not get appropriate answers.

The next task is to identify the type and number of representative individuals to be interviewed and the type and number of documents to be reviewed that will enable the team to gather sufficient information to address the issues. Before scheduling interviews and document reviews, the assessors can consider if a specific job or document gives them objective evidence for the issues. They can then consider how many interviews or document reviews are needed, relative to the size of the organization, to make a representative finding. The individuals and documents may be involved with program-level or project-level quality activities. Examples of job category sources for interviews are listed in Figure 3.

It is not necessary at this point to name specific individuals to be interviewed; identifying job titles or job functions may be all the assessment team can accomplish given the information on hand. The goal at this point is to be specific enough in identifying the interviewees so that the assessment team has reasonable assurance that these individuals can provide the information that is needed to address the assessment issues.

Some considerations for selecting interviewees who are appropriate for the issues may include: (1) their availability; (2) their experience; (3) their knowledge of the issues; (4) how long the individuals have held their positions; and (5) the extent that these individuals represent the entire pool of those in similar positions.

For a large program, individuals to be interviewed are selected to get adequate coverage of issues, programs, and job types within the allocated assessment resources. The assessee may recommend specific individuals to be interviewed. This practice is generally acceptable if the individuals' characteristics such as on-the-job experience meet the assessment requirements. If all of the interviewees are selected by the assessee, the final assessment report may need to include qualifying text such as "If the interviewees are representative of your program, then"

As is the case with identifying interviewees, the assessment team specifies the documents to be reviewed in sufficient detail to ensure that the documents are accessible and the assessment issues will be addressed effectively. Document selection criteria include: (1) being representative of the document types most frequently prepared by the organization; (2) being representative of the work performed by the organization; and (3) having importance relative to the organization's mission. If an organization has changed its quality policy or procedures, select documents that reflect the changes being assessed. When selecting particular projects for document review, make sure these projects cover a time period and implementation stage that are appropriate for the issue being addressed. For example, projects just getting underway would not be appropriate for a review of data quality assessment procedures.

Examples of documents and specific features of the documents that may be reviewed to prepare for and during an assessment are presented in Figure 4. Other documents, such as financial

Examples of job category sources for interviews during an assessment:

- senior managers (e.g., division directors, office directors)
- middle managers (e.g., branch chiefs, section chiefs)
- project managers (e.g., project officers, principal investigators)
- quality assurance managers (program-level and project-level)
- data analysts (e.g., statisticians and modelers)
- data handling specialists
- laboratory managers/staff

Figure 3. Example Job Categories for Interviews

673 assistance agreement decision packages
674 and contract specifications, also may be
675 relevant to the assessment.

676 EPA QA Annual Reports and
677 Work Plans summarize resources
678 available for quality assurance in EPA
679 programs. As part of the assessment,
680 these documents can be compared to
681 the Quality Management Plan or
682 verified on-site to ensure that the roles
683 and responsibilities are covered as
684 described in the Quality Management
685 Plan. For example, the number of full-
686 time equivalents (FTEs) designated for
687 QA staff could be verified against
688 possible vacancies or assignments to
689 non-QA activities when on-site or
690 checked against the work reported on
691 QA Project Plan reviews,
692 internal/external assessments, and
693 training.

694 To assess the use of resources
695 for oversight, lists of both external and
696 internal assessments in the previous
697 year's work plan could be checked to
698 see if they agree with lists of completed
699 reports and the requirements of the
700 Quality Management Plan. These
701 documents give indications about the
702 adequacy of resources and the
703 commitment of the organization (for
704 example, if less work is performed than
705 was planned). They would be useful in
706 targeting issues (for example, if no
707 internal assessments are reported,
708 why?).

Example documents and their specific features that may be reviewed:

- Quality Management Plans
 - signature and date
- QA Project Plans
 - signature (QA Manager or designee), date
 - data quality objectives/systematic planning process
 - required elements relevant to assessment:
 - (a) training/expertise for field personnel; and
 - (b) oversight of field activities
- QA Review Forms
 - signature (QA Manager or designee), date
 - project title, number
 - obtain/check proposal to verify credibility of a “no measurements” claim
- QA reports to management
 - quality problems described
- internal quality policy and guidance documents
- reports of internal assessments (e.g., assessments of quality systems, technical systems audits, surveillance, performance evaluations, audits of data quality, data quality assessments, peer reviews)
 - purpose of assessment and date
 - assessor, title, signature, date
 - personnel (expertise), process
 - findings, corrective actions
 - assessee/responsible party
 - process for reporting/verifying completion of corrective actions
- external assessments reports by the assessee
- work products (e.g., final project reports)
- QA working papers
- training records
 - records are current
 - training is appropriate for responsibilities
- standard operating procedures
 - signature, date, and revision number
- standardized methods.

Figure 4. Example Documents and Features To Review

3.7 ALTERNATIVES TO ON-SITE INTERVIEWS

The decision to use interviews or other information collection tools involves considering their comparative advantages and disadvantages. Examples of other information collection tools are videoconferencing, telephone interviews, and return mail questionnaires. More information about these tools can be found in the literature on survey research methodology (e.g., GAO, 1991 and 1993; De Leeuw, 1992).

Each tool has its own blend of strengths and weaknesses. Because of their flexibility and potential, face-to-face interviews have been considered superior to telephone interviews and mail surveys. Information collected in face-to-face interviews has often been considered to be less suspect than information obtained by other tools such as telephone interviews. However, the other tools do not incur the travel costs that are associated with face-to-face interviews.

3.8 PREPARATION OF THE ASSESSMENT PLAN

The assessment plan is a short document prepared by the assessment team under the direction of the assessment team leader. It is a concise summary of the assessment and the manner in which the assessment will be conducted. It gives adequate information to the assessee about what activities are expected to occur during the assessment and a schedule for these activities. An example outline of an assessment plan appears in Figure 5.

The assessment plan includes the authority and criteria for the assessment, the purpose and scope of the assessment, the assessment issues, and the organizations that will be visited during the assessment. The plan also includes details, such as a schedule of assessment activities, specific personnel (or job positions) to be interviewed, and specific files and documentation that will be reviewed during the assessment. The assessment plan states clearly what will and will not be done regarding confidentiality and the dissemination of the assessment findings. The assessment checklist can be appended to the assessment plan. The checklist contains the specific technical questions to be asked of specific interviewees and the specific documents to be reviewed, if appropriate.

The assessment plan is discussed informally with the assessee before the assessment to negotiate schedules, identify needed documents and records, and confirm the availability of interviewees and meeting space. Planning and scheduling interviews and document reviews should consider both what can realistically be covered within the allotted time and what needs to be covered to adequately characterize the assessed system.

The assessment plan specifies whether the assessment team will present recommended corrective actions as part of the assessment report or whether the assessee management will develop these corrective actions based on the assessment findings.

Assessment Plan		
Assessee:	Organization:	EPA Region 12, Division of Solid Waste (DSW)
	Location:	Juneau, Alaska
	Senior Official	Jim Schnee, Director, Division of Solid Waste
	QA Manager:	Mary Eulen, Division Quality Assurance Manager
Authorizing Entity:	William Shipley, Regional Administrator (RA)	
Review and Concurrence by:	Pat Pack, Deputy Regional Administrator (DRA)	
Assessment Team: Leader:	Susan Davis, Regional QA Manager	
	Assessor:	Emmanuel Kealeboga, Division of Oil and Gas Remediation
	Assessor:	Margaret O'Connor, Division of Arctic Air
Anticipated Dates of Assessment:	January 2-4, 2002	
Authority To Conduct Assessment:	EPA Order 5360.1 A2 (May 2000)	
Criteria for Assessment:	Quality Manual, applicable assistance agreements, contract regulations	
Purpose and Scope of Assessment:	Implementation of DSW quality management plan in Juneau branches	
Issues Identified:	QA project plan review and approval, data quality assessment process, data quality objective process, training, and record keeping	
Personnel To Be Interviewed:	Branch QA Coordinators, 4 project officers per branch (2 with data collection/analysis completed, all in branch at least 1 year), DSW QAM, DSW supervisor, DSW training coordinator, and DSW statistician	
Documents To Be Reviewed:	Interviewed project officer files including all QA documentation (e.g., QA project plans, standard operating procedures, oversight records, data analysis records, project reports), QAM files including QA project plan reviews, project implementation and report reviews, and training records	
Anticipated Opening Meeting:	January 2, 2002, 8:00 a.m.	
Opening Meeting Participants:	DSW managers	
Anticipated Assessment Schedule:	9 a.m. to 4 p.m. each day, one branch per day	
Anticipated Closing Meeting	January 4, 2002, 4:30 p.m.	
Closing Meeting Participants:	DSW Managers	
Anticipated Reporting Schedule:	February 2, 2002	
Report Routing Pathway:	RA, DRA, Jim Schnee, Mary Eulen, DSW Managers	
Confidentiality of Findings Report:	None	
Dissemination of Findings Report:	Internal only	
Provision for Recommendations:	Yes	

Figure 5. Example Contents of a Plan for Assessing a Quality System

3.9 REVIEW AND APPROVAL OF THE ASSESSMENT PLAN

Once the assessment plan has been completed by the assessment team, it is usually submitted to the authorizing entity for concurrence and approval unless it is routine. Transmitting the plan well before the assessment date allows:

- the authorizing authority to raise questions about the plan or discuss the rationale of the proposed approach
- the authorizing entity to be informed explicitly of any nonroutine aspects of the assessment
- the assessment team to revise the plan and to resubmit it for approval if sufficient concerns or issues are raised by the authorizing authority, which is unlikely to occur if the assessment team has been thorough in its planning
- the assessment team to resolve all concerns or issues before proceeding any further.

The authorizing entity approves the assessment plan before the assessment proceeds. The concurrence of the authorizing entity:

- affirms the authority, credibility, and scope of the assessment with the assessee and with the persons who will receive the final assessment report
- encourages authorizing entity “buy-in” and engenders a sense of ownership of the process
- assures the authorizing entity that the assessment will accomplish the expected objectives
- encourages support from the authorizing entity for any disputed findings and for implementation of recommended corrective actions.

3.10 CONFIDENTIALITY

The confidentiality and dissemination of the assessment findings and other assessment documents are addressed during planning for the assessment and are described in the assessment plan. All involved parties (i.e., the assessor, the assessee, and the authorizing entity) are in agreement regarding confidentiality issues prior to the start of the assessment. Generally, assessment findings are released only to the involved parties.

Any information that the assessee claims as confidential business information (CBI) is treated as described in the relevant regulations. Information of concern may include:

- proprietary technical information or trade secrets
- financial information

- personnel records.

Assessors may also have access to enforcement-sensitive information, which is treated with the appropriate confidentiality. The Freedom of Information Act may, in some cases, be used to obtain assessment findings and other assessment documents. Personnel records may include records of training and proficiency demonstrations. Fiscal reports may be reviewed during an assessment and may require special confidentiality approaches.

3.11 ASSESSMENT COORDINATION AND LOGISTICAL ARRANGEMENTS

Many assessments require travel and thus a fairly tight, workable schedule. Adherence to a workable schedule requires coordination between the assessment team and the assessee. The assessment team leader usually makes logistical arrangements, such as finalizing the assessment dates with the assessee, arranging lodging, and making travel arrangements. The assessment team will typically ask the assessee to provide a meeting room on-site. Security clearances, special site passes, access to the assessee's facility, and parking passes are arranged in advance. Health and safety concerns will be considerations if the assessment requires entrance to laboratory or mechanical areas. For assessments involving travel, the assessment team leader informs the assessee's QA Manager of logistics such as travel schedule, lodging, and a telephone number where the assessment team can be reached.

3.12 FORMAL NOTIFICATION OF THE ASSESSEE

After the assessment plan has been approved by the authorizing entity, it is formally transmitted to assessee management. If not done in previous communication (see Section 3.3), this document establishes the authority for the assessment, identifies the assessment team members and their affiliations, and defines the assessment scope, the assessment criteria, and a tentative schedule. An example of a formal notification letter is provided in Figure 6.

A no-surprises approach of keeping the assessee informed improves cooperation during the assessment, so the assessee usually receives the assessment plan at least two weeks before the assessment. Because any necessary corrective actions will be implemented by the assessee's management, management's involvement from the start of the assessment is essential. The assessment team may also elect to send a copy of the assessment checklist to the assessee prior to the assessment. After the assessee acknowledges the notification, the schedule for the interviews and document reviews is finalized and the assessment team's logistical arrangements are completed.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

**Region 12
Juneau, Alaska 99801**

December 15, 2002

Julia Bennett, Commissioner
Alaska Department of Environmental Conservation
410 Willoughby Avenue, Suite 303
Juneau, AK 99801-1795

Dear Commissioner Bennett:

EPA Order 5360.1 A2 (2000), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, requires all EPA-funded organizations collecting and using environmental data to develop and implement adequate quality assurance (QA) and quality control (QC) practices to ensure that the data are of the type and quality needed for EPA decisions. These practices are documented in Quality Management Plans (QMPs) that are reviewed by Regional quality assurance staff and approved for implementation by the Regional Administrators.

One of the quality management responsibilities of the Region is to provide periodic oversight and assessment of the implementation of the Quality System in Region 12. In compliance with this responsibility, the Region will conduct an assessment of DEC's quality system to determine:

- (1) compliance with the DEC QMP or, in the absence of this plan, compliance with EPA QA requirements for the QA and QC practices in support of EPA-funded environmental data collection and use, and
- (2) the suitability and effectiveness of the quality practices actually being implemented by DEC.

The assessment process will include interviews of DEC managers and staff and related document reviews regarding QMP implementation. The criteria for the assessment are EPA requirements, DEC's QMP, referenced procedures, and DEC's annual QA Report. The team plans to conduct the assessment during the week of January 27, 2003. Logistical details and the schedule for interviews and document reviews are under discussion with the DEC QA Manager, Mark Zimmerman. The assessment plan will be sent to you at least two weeks before the assessment.

The assessment team will be composed of Susan Davis, Regional QA Manager, who will serve as team leader, and Michael O'Brien of the Quality Assurance Staff. Marsha Brown of the Frozen Waste Division will provide expertise in frozen waste programs. They plan to brief DEC management on the scope of the assessment during an opening meeting on January 27, if that is convenient.

I intend for this assessment to be helpful to your organization so that we may learn from our experience and improve the DEC's quality system. I look forward to the successful completion of this assessment.

Respectfully,

William Shipley
Regional Administrator

cc: Mark Zimmerman, DEC Quality Assurance Manager

Figure 6. Example Formal Notification Letter

3.13 PREPARATION OF CHECKLISTS AND OTHER ASSESSMENT AIDS

The planning process usually includes the development of assessment checklists and other written assessment aids, which incorporate all of the issues that were identified. They are used by the assessment team to organize the interviews and the document reviews and to record the information that they collect. These aids are specific to the scope and issues of the assessment and are individually tailored for each assessment. They are a systematic means to obtain and record objective evidence about the quality system that is not, but could have been, documented by the assessee. They help to ensure the objectivity, reliability, consistency, and completeness of the assessment. They can be used to help the assessor track some basic questions:

- What is the assessee doing on this issue?
- Is there evidence to support the assessee's statements?
- Does it work? Is it a noteworthy practice, just OK, or a serious problem?
- How does what the assessee is actually doing on this issue compare to what the assessee says is being done?
- Is enough of the assessee's staff doing this to allow something definitive to be said?

In interviews, assessment issues are discussed with an interviewee. The interviewee's responses can be recorded in a checklist tailored for that interview and in supplemental notes. The goal of the interview is not to complete the checklist, but to obtain objective information that addresses the issues. The questions generally are tied to the audit criteria to simplify report preparation and to achieve the goals of the assessment. See Appendix C for example interview questions for developing and mature quality systems and for different job classifications. An example assessment checklist appears in Appendix D.

The questions to be asked in interviews or investigated in document reviews are formulated to fill gaps in the previously collected information about the quality system and assessment issues, and to verify this information. It may be helpful for the assessors to note previously studied information that needs to be verified. Checklist questions have the following characteristics, some of which are applicable only to interviews:

- The questions are specific to the quality system being assessed.
- They are relevant to the assessment being conducted and have a good probability of yielding useful information.
- They are relatively easy to answer and do not cause undue burden or discomfort to the interviewee.
- They concern a single piece of information. (It is better to have more questions with a narrow focus than fewer broad questions that may be difficult to answer succinctly.)
- They address objective, measurable characteristics of the quality system.

- They are clear and comprehensible to the intended interviewees.
- They have real answers, even if some answers may be “I don’t know” or “I do not have enough information to answer.”
- They do not lead the interviewee toward a particular answer by the use of biased language.

Typically, open-ended questions are preferable to close-ended (i.e., yes/no) questions for interviews because they allow the interviewee to explain the answer more completely. The questions may be qualitative or quantitative as needed. They address quality practices that are described in the assessee’s Quality Management Plan or other quality documents or requirements. They address specific, observable activities that are to be performed, rather than the more general principles that may be hard to define in practice. For example, if the assessee’s quality documents state that records will be kept in a central, locked file, “How are the quality records stored?” is a better question than “Are good record-keeping procedures being followed?” Time spent in the planning phase developing appropriate assessment questions can save time while on-site.

The use of generic checklists for assessments is discouraged. A “one size fits all” checklist may overlook unique features of the specific quality system being assessed. Although a checklist from one assessment may serve as the basis for developing a checklist for a subsequent assessment, it is not appropriate to reuse unrevised checklists. The process of developing a checklist that is tailored to a specific quality system helps the assessment team to develop a more complete understanding of this quality system and to be better prepared to conduct the assessment. It is also a way for assessment team members to share their expertise on specific issues if they devise the questions and note information for the rest of the team. Under one possible format for assessment checklists, the questions include a citation of the specific section of the quality document that is the basis for the question. They may also include the quality document’s specifications for acceptable performance or compliance.

To ensure that the appropriate source for the information is used, prepare different assessment questions for each different job category of interviewee (senior manager, line manager, QA staff member, project officer, etc.) and for each different document type (Quality Management Plan, QA Project Plan, standard operating procedure, etc.). A question may be relevant to an assessment issue and yet be useless if the wrong person is asked or the wrong document is examined. For more efficiency, remove redundant questions caused by addressing issues that use some of the same information from interviews and document reviews.

If an assessment has many issues, interviewees, and documents, it may be helpful to prepare a matrix, which is a variation of a checklist. The matrix is an information collection tool to increase the understanding of the quality system by the assessor and to keep track of all of the information gathered during assessment planning, on-site interviews, and document review. A matrix can be used more directly than can a checklist to help prepare a complex assessment report.

875 A matrix presents the important assessment issues in a format that consolidates the findings from
876 various interviewees in one place. It could list, at least: (1) the issue with the assessment criterion or
877 justification; (2) the information discovered in preassessment document reviews with any notation of
878 things to verify; and (3) space for the summary of on-site interviews and document reviews. It may also
879 be helpful to include space for comments from the analysis of the evidence, whether there is a negative
880 or positive finding and/or a noteworthy effective practice. An example matrix appears in Table 2.
881 Additional information regarding interviewing skills is given in Appendix B.

882 When completed, the checklists and other assessment aids demonstrate that the assessment
883 was conducted, that it was conducted in an orderly and complete manner, and that all assessment
884 issues were addressed. Assessors will probably find it difficult to retain in memory the details of every
885 interview or document review so it is important to record the information while it is still fresh in the
886 assessor's mind. Completed checklists and other assessment aids also provide an information base for
887 assembling findings for the closing meeting and the assessment report.

Table 2. Example Row of Working Paper Matrix for Recording Assessment Observations

Issue from Audit Plan or Other Source with Description/Rationale	Requirement (cite references)	Quality Management Plan (QMP) Compliance with Requirements (cite references)	Interview/Document Compliance with QMP? (cite notes, copies, and references)	Analysis and Positive or Negative finding (effective practice?)
<p>I. QA documentation in EPA Contracts:</p> <p>A. Effectiveness in identifying data collection activities</p> <p>B. Verifying process for reviewing and approving QA Project Plan before data collection begins</p> <p>C. Verifying that any Agency report (resulting from a contract in this case) includes the requisite QA section on limitations on the use of the data</p>	<p>A. QA Review Form attached to each scope of work for contract to identify data collection activities</p> <p>For contracts over \$500K, QA officer must be on proposal technical evaluation panel (TEP) (Order 5360.1 and E4)</p> <p>B. QA Project Plan review and approval by QA Manager or delegated person, dated before data collection activities begin (Quality Manual)</p> <p>C. Report review by QA Manager or delegated person, dated before publication (Quality Manual)</p>	<p>To be filled in during planning with information on how the processes in the available documentation (QMP, for example) compare to the requirements</p>	<p>To be filled in from interviews and document reviews, although it may be useful beforehand to list the expected evidence from documents (contracts, QARFs, QA Project Plans, review tools, oversight documentation, reports) and interview topics (processes and qualifications, participation on TEPs)</p>	<p>To be filled out after completing interviews and document reviews</p>

CHAPTER 4

CONDUCTING THE ASSESSMENT

After the assessment planning is complete (as described in Chapter 3), the assessment is conducted. Figure 7 indicates the steps for actually conducting the assessment, which are described in more detail in this chapter.

The on-site portion of an assessment may last for a few days. The assessment team remains aware that the assessment is disruptive of the normal activities of the assessee. The assessment team uses due professional care in conducting the assessment. The assessment team is considerate of the interviewees' scheduling constraints and is as professional and efficient as possible.

At least once each day during a multiday assessment, the assessment team meets privately to share information gathered so far and to discuss potential findings and possible problem areas. If contradictory information has been gathered, more information may need to be collected to resolve the contradiction. The assessment team may need to discuss and possibly revise the assessment schedule. In the discussions of assessment schedule, the assessment team leader will make sure that the assessment stays on track and that team members are not distracted by minor issues. The team members need to be able to contact the leader between the daily meetings in case they encounter a problem they cannot address.

Similarly, the team may need close contact with the assessee to facilitate scheduling changes. If needed, the assessee will provide staff to escort the assessment team and see to their needs for communications, photocopying, etc. If possible to do so within the assessment schedule and if appropriate for the particular assessment, daily briefings between assessors and assessees can be held. These provide an opportunity to map out the next day's schedule and to ask for additional documents. If daily briefings are not possible because of scheduling constraints, it may be appropriate to contact the assessee's QA Manager and to establish a time to talk with the QA Manager when needed. Many assessors also find it useful to meet with the assessee's QA Manager before the closing meeting to discuss the findings.

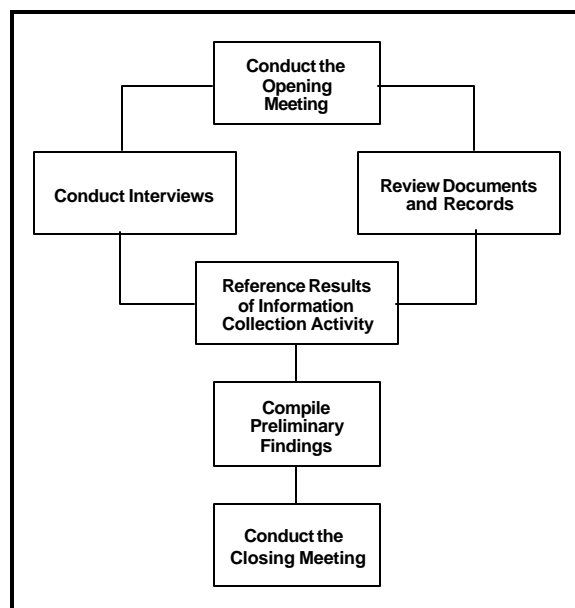


Figure 7. Flow Chart for Conducting the Assessment

4.1 CONDUCT THE OPENING MEETING

A successful opening meeting with the assessee's senior management, QA Manager, and other staff as appropriate is critical to the success of the assessment. The assessment team keeps a list of attendees with name, titles, affiliations, phone numbers, and mailing and e-mail addresses for post-assessment contacts. If some of the assessees are anxious or irritated at having to spend time on the assessment, the assessment team leader can make every effort to reduce the anxiety level by focusing on the purpose of the assessment and by emphasizing that the team will minimize disruptions of the organization's normal activities.

The opening meeting is an opportunity to describe what will be done, why, when, and how during the assessment. An example agenda for this meeting is presented in Figure 8. The meeting generally starts with introductions and thanks for ongoing cooperation with the assessment. The assessment team leader will introduce the assessment team members and review the objectives of and authority for the assessment, assessment scope and criteria, the principal questions to be asked during interviews, the expectations for the reviews and reports, and the process for assessment report review. If this assessee organization has been assessed previously by the same organization, any changes and additions to the process since the previous assessment will be noted, so the meeting may take less time. Afterward, the assessee management will be invited to ask questions about the assessment. There are no hidden agenda and surprises. Questions are answered directly, truthfully, and without hesitation. The entire meeting lasts no longer than 30 to 45 minutes. At the conclusion of the opening meeting, the assessee provides any last-minute changes to the list of interviewees and the schedule for the interviews.

Opening Meeting Agenda with Senior Management and QA Manager

1. Introductions
2. Authority for and purpose of the assessment (if needed, for repeat assessment)
3. Assessment scope, criteria, and schedule for interviews and document reviews
4. Assessment reporting process (with any differences from previous assessment)
 - Closing meeting
 - Report content and schedule
 - Report review process and schedule
 - Corrective action plan and implementation tracking
 - Final report and distribution
5. Questions and answers
6. Conclusion

Figure 8. Agenda for the Opening Meeting

4.2 REVIEW DOCUMENTS AND RECORDS

Information is gathered by reviewing written documentation, such as documents and records, during the assessment. Assessments typically verify records for evidence of compliance with the quality system requirements, as stated in the Quality Management Plan. Documents are examined to find

relevant data and records and to supplement information collected in interviews. Planning documents, prior assessment reports, and standard operating procedures are examples of the types of documentation that are included in the document review. Some of these documents may have been reviewed by the assessment team during the planning phase of the assessment and do not need to be reviewed on site. As discussed below, working papers, such as completed assessment checklists and matrices, are prepared during the assessment to keep track of the sources of all information.

During the document review, the assessment team collects information that answers specific questions and topics in the assessment plan. The documents to be examined have been identified in the assessment plan to allow the assessee to assemble the documents before the assessment, making the assessment team's review more efficient. Including the preliminary list of documents to be examined in the assessment plan helps the assessment team track the document review process during the on-site portion of the assessment. It is possible that additional documents will be identified and requested for review during the assessment. The assessment plan also lists the documents to be provided to the assessment team prior to the assessment and the time frame for receiving those documents. However, organizations may document their quality system and its components differently, or may use different titles for their documents. The list of quality records and documents in Section 3.6 is a starting point for the types of documents to review.

The following are some generic questions for documents being reviewed:

- If the document is required for the quality system, does it actually exist? If not, do plans exist to prepare the document? Does the assessee need assistance in preparing this document?
- Is a copy of the document readily available for review by the assessor?
- Is the document stored in an organized fashion?
- Is the document accessible to the staff who need to use it? Do they use it?
- Is there evidence (e.g., signature page entries) that the document has been reviewed and approved in the manner specified for the quality system?
- Is the document up to date? If it has to be updated periodically, is this being updated according to schedule?
- Is the document in a format that is reasonable for its intended purpose? Is it readable?
- Does the document cite the appropriate quality system requirement?
- Does the document do what it is supposed to do?
- Does the document present evidence that the quality system is functioning as required?

4.3 CONDUCT INTERVIEWS

The basics of an assessment interview are described in this section. Appendix B gives more information on interviewing techniques and skills. Examples of interview questions are presented in Appendix C, and Appendix D is an example assessment checklist.

During interviews, emphasize that the quality system is being assessed, rather than the individuals in the organization. Interviewees can be reassured that their job performance is not being judged. The organization's management can set an example for the staff by projecting a positive attitude toward the assessment and the assessors.

Assessment interviews are generally limited to one hour. As is discussed in Appendix B, when possible, given the staffing, time, and other resource constraints, many assessment teams prefer to have two assessors participate in all interviews. The assessment team needs to remain flexible during the interviewing process to accommodate last-minute changes resulting from scheduling conflicts, retrieval of documentation, and so on. All of the interviewers are introduced at the start of the interview. One of the interviewers briefly discusses the purpose of the assessment, how and why the interviewees were selected, what information is needed from the interview, and what will be done with the information. One useful point to make at the start of the interview is that the assessment report will not attribute specific comments to specific interviewees. The interviewees are allowed an opportunity to ask questions. Assessors use the assessment checklist as a guide, not a script to be rigidly followed.

Generally, only one interviewee is included in each interview, but there are circumstances in which more than one interviewee will be included. For instance, some assessee management may insist on having their QA Manager or a management representative attend selected interviews. Also, when there is a team working together on a project, it may be expedient to interview the team together so that all of the questions can be answered at one time. During the interviews, the interviewer is careful to ensure that the information is provided by the interviewee without prompting by the manager or any other management representative who may be present. While the manager or a management representative are welcome to attend interviews, they are not allowed to direct or signal the interviewee what the acceptable answer is from their perspective.

Assessment questions do not lead the interviewee toward a specific response that the assessor expects to hear because the assessment findings will become biased. Leading questions can be avoided by making them open ended rather than close ended. The following close-ended and open-ended questions illustrate how poorly designed assessment questions may produce a biased response:

Close-ended: Are appropriate technical experts involved in the project planning process?

Open-ended: What is the role of technical experts in planning your office's projects?

Because an open-ended question provides no structure for the answer, the interviewee may provide information that is not directly relevant to the issue at hand. The interviewer keeps the interviewee focused on the issue.

At the end of each interview, the interviewer repeats how the assessment findings will be used, mentions the possibility of follow-up, asks if there is anything more that the interviewee would like to

add, and then thanks the interviewee for his or her time. Interview times are structured so that after each interview, the interviewer(s) has sufficient time to review and complete notes before the next interview.

4.4 REFERENCE RESULTS OF INFORMATION COLLECTION ACTIVITY

During an assessment, each assessor compiles working papers that record observations from interviews and document reviews as well as the sources of these observations. These working papers are retained by the assessors as evidence for all statements made in the assessment result reports. The technique of referencing the assessment findings to the working papers imposes a high standard for note taking. The assessment team understands the need to record all information accurately during interviews and document reviews. The assessment checklist can function as working papers provided that sufficient space for notes is available on the form. Taking good, organized notes during the assessment, particularly notes geared to the assessment issues, will make preparing the report easier.

4.5 COMPILE PRELIMINARY FINDINGS

Before the closing meeting, the assessment team members come together to review and summarize their observations from the interviews and document reviews and discuss the preliminary findings. One approach to compiling team findings is to have each team member nominate candidate findings and then discuss the specific observations supporting each candidate finding. This approach allows the team to resolve any uncertainties or inconsistencies regarding individual findings and to determine the relative importance of individual findings. The assessment team leader has final authority for decisions on the findings, but all team members are expected to have input. It is important that findings be prioritized according to their significance so that important findings are not lost within a list of trivial concerns. Remember that the assessment plan can assist with the interpretation of observations and aids in identifying findings.

The initial findings are presented in the closing meeting, but it is also a good idea to meet with the assessee's QA Manager or his or her designated point of contact before that meeting to gain the organization's perspective on issues and to share details about other issues identified during the assessment that may not be of interest to management.

The initial findings may have limitations. For example, notes may not have been completely studied and discussed. If documents are being taken for further study, new information may be identified that will change the interpretation and lead to different or additional findings. The assessment team will commit to contacting the assessee if findings change.

The assessment team leader develops a summary or overview of the assessment and the preliminary findings. The assessment team is well prepared to discuss the findings at the closing

meeting. Development and implementation of corrective actions are the responsibility of the assessee, but the assessment team can provide technical assistance, when appropriate.

4.6 CONDUCT THE CLOSING MEETING

Generally the closing meeting is attended by the same group that attended the opening meeting. Important talking points to be stressed during the closing meeting include:

- findings from the assessment and any relevant observations are preliminary
- findings may change if the review is incomplete (particularly, if the findings of individual assessors have not yet been generalized to the findings for the entire quality system—this may not be available at the time of the closing meeting)
- the assessee will be contacted if the findings change or if more information is needed; findings will be made available to the assessee before the report is finalized
- findings can be addressed by the assessee before the report is finalized
- technical assistance can be provided by the assessment team for determining appropriate corrective action, if requested
- confidentiality and dissemination of assessment findings, and the schedule for reports are discussed.

Closing Meeting (Same attendees as Opening Meeting, or assessee's choice)

1. Introductions (if needed) and appreciation for assistance and cooperation
2. Brief discussion of deviations from the assessment plan (if needed)
3. Preliminary findings with discussion of corrective action (if needed)
 - Addressing findings before final report
 - Technical assistance and recommendations
4. Procedure for contact if findings change
5. Assessment reporting process review (if needed)
6. Questions and answers
7. Conclusion

The participants are thanked for their cooperation, time, and help. An example agenda for the closing meeting is presented in Figure 9.

Figure 9. Agenda for the Closing Meeting

CHAPTER 5

REPORTING AND FOLLOW-UP

After the assessment is complete, the assessment team summarizes the findings in a timely manner. The report will have more of an effect on the quality system if it is received while the assessment is still fresh in the assessee's mind. An assessment report is prepared, reviewed, and then submitted to the assessee, typically to check the report for accuracy. After comments by the assessee are resolved, the final assessment report is prepared. Figure 10 presents the steps for reporting and follow up.

5.1 EVALUATING COLLECTED ASSESSMENT INFORMATION

Soon after completing the on-site portion of the assessment, each team member reviews all his or her collected materials, working papers, and notes, and prepares preliminary findings. The assessment team leader consolidates the preliminary findings and circulates them to team members, who add more material and can suggest new findings based on additional review of their notes and other materials obtained during the assessment. Findings are tested against the evidence, such as the documents and records reviewed. At this point, it is critical that the team determine whether the findings are relevant to the assessment goals. The team needs to reach consensus on the message and format, and determine if the findings are clear, coherent, and persuasive. To avoid surprises, the assessee is contacted to discuss any new findings, as had been previously arranged during the on-site portion of the assessment. The assessee's QA Manager or designee can be contacted, if additional information is needed, with copies of any requests sent to the assessee's management.

As discussed in Section 4.4, referencing is a technique for controlling the quality of assessment reports. All statements are substantiated by notes taken during interviews or review of documentation. Assessment team members provide highlighted notes and relevant pages of reviewed documents to the report writer to support findings.

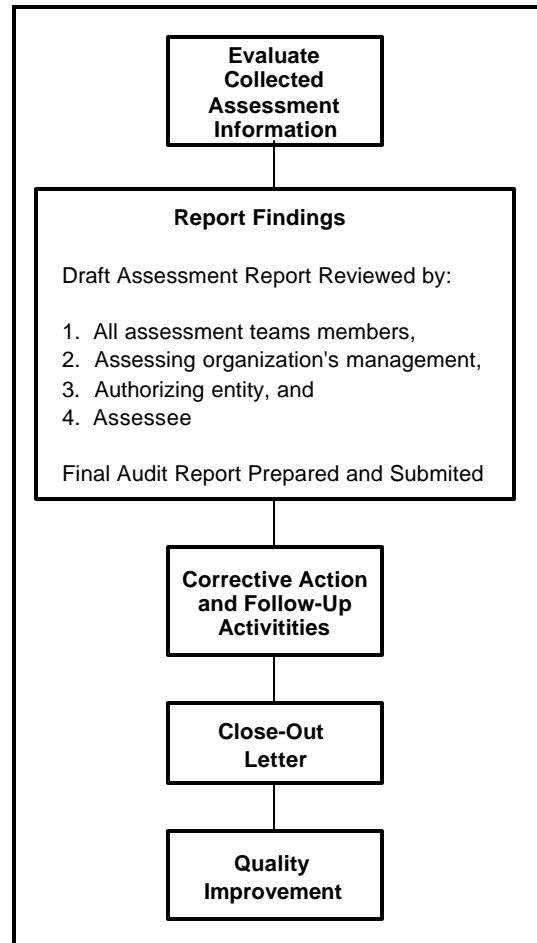


Figure 10. Typical Steps for Assessment Reporting and Follow-up

5.2 REPORTING FINDINGS

The objective of an assessment report is to communicate assessment findings to the proper levels of management. Different organizations use different formats, but many of these formats clearly state the type of assessment, the assessor, the assessee, what was assessed, the findings, and, if requested by the authorizing entity, the conclusions and recommendations. An example format is given in Figure 11. The assessment team leader is primarily responsible for producing the assessment report, but it is a collaborative effort.

1. Background, Purpose, and Scope
 2. Summary and Findings
 3. Corrective/Response Actions and Recommendations
- References
Appendices
- A. Assessment Plan
 - B. List of Personnel Interviewed
 - C. List of Documents and Records Reviewed
 - D. Corrective Action Plan

Figure 11. Example Assessment Report Outline

Many organizations prepare a draft assessment report for review by the assessee, while others present an oral report at the end of the on-site portion of the assessment in lieu of a written draft report. A draft report provides the assessee with an opportunity to comment on the written document before it is finalized, but this approach does require additional time. For some assessments, the criteria and issues may be so straightforward as to permit concluding the assessment on site with a presentation of a streamlined report, which does not need additional explanation. This method, like more conventional reporting, would warrant up-front agreement with both the authorizing entity and the assessee.

Use a standard report format with boilerplate text, when appropriate, to make report preparation easier. Clear and concise writing, without unsubstantiated generalizations or ambiguous remarks, facilitates understanding and appropriate action by the assessee. Avoid words that could be misinterpreted. To achieve the goal of quality improvement, significant deficiencies are best addressed in a constructive manner. The report includes both positive and negative observations, when appropriate. In the report, the organization's actions are discussed, but not the actions of specific individuals, because individual interviewees are not quoted in the report.

Assessment findings and any need for corrective actions are prioritized relative to the assessee's overall goals. Any recommended corrective actions are clearly presented. Recommendations for addressing corrective actions are provided to the assessee only if outlined in the approved assessment plan or upon request by the authorizing or entity assessee. An unsolicited recommendation carries a risk of being accepted and implemented, but then leading to unanticipated negative consequences. Any recommendations that are not specifically linked to any negative findings are identified and justified.

When the need for corrective actions is identified, it is helpful to attach a chart for the assessee to fill in that gives a corrective action plan with a proposed schedule. The assessment team may provide a shell of the corrective action plan in the draft report that includes the specific findings; an example of this shell is given in Table 3. If no corrective actions are identified, the report with recommendations can be recorded and sent to the assessee to check for accuracy.

Table 3. Example of a Shell of a Corrective Action Plan

Finding Number	Report Finding	Corrective Action	Responsible Official	Due Date
1	Oversight of field and laboratory activities is not routinely implemented as described in the Quality Management Plan.			

Typically, the draft report is reviewed by all team members, then by the assessing organization's internal management, then by the authorizing entity. Finally, the report is transmitted to the assessee with a transmittal memorandum or letter. When the report is sent to the assessee for comment, a specific date for receiving comments is stated in the transmittal memorandum or letter.

The assessee completes the corrective action plan and submits it to the assessment team for approval, generally along with any other comments on the draft report. This submission sets the stage for follow up with specific commitments by management. The corrective action plan can specify the organizational positions of the individuals who are responsible for implementing the corrective actions. If agreed upon, the completed corrective action plan may be sent back from the assessee later than the comments on the draft assessment report.

To finalize the report, the assessment team incorporates any relevant comments from the assessee when appropriate, corrects any identified factual errors, and resolves any disputes if possible. Any disputes are resolved at the lowest administrative level possible and in accordance with the dispute resolution process for the assessment system. If the assessee does not respond in a timely fashion, the assessment team leader will contact the assessee QA Manager or designated point of contact. It may be necessary for the assessment program manager or the authorizing entity to play a role in dispute resolution. After final approval for the report is received from the authorizing entity, it is distributed as previously agreed in the assessment plan.

5.3 CORRECTIVE ACTION AND FOLLOW-UP ACTIVITIES

The development and implementation of corrective actions are the responsibility of the assessee, but the assessment team can provide technical assistance in developing appropriate corrective

actions. As noted in the previous section, identifying both a deadline and responsible person for implementing corrective actions will facilitate appropriate actions being completed. Regular reporting may be established, or the assessors may be assigned to periodically contact the organization's QA Manager. Another means of follow up can be to have a designated assessor check progress with the assessee within a designated time frame on a particular issue. The assessors also make sure that they provide any promised assistance or reviews.

Documenting the follow-up activities will ensure that a subsequent assessment team will be able to track activities. Often, this follow up is accomplished during subsequent assessments. In addition, this follow up may be done by receiving and reviewing reports summarizing the corrective actions or by tracking them in routine reports, such as the QA Annual Reports and Work Plans that are submitted by EPA Program Offices, Regional Offices, and National Research Laboratories. These reports document activities of the quality system or revisions to the Quality Management Plan.

5.4 FORMAL CLOSE OUT OF ASSESSMENT

After all assessment activities are complete, the assessment is closed. This occurs after a response from the assessed organization, an acceptable corrective action plan (if necessary), and verification of completion of corrective action are received. The assessment file is reviewed to ensure that it is complete before it is archived. The assessment team leader may issue a close-out letter stating that all actions associated with the assessment are complete. The close-out letter is added to the file. Figure 12 presents an example of a close-out letter. Not all organizations use a formal close-out letter; some prefer to document close-out of assessments in QA Annual Reports and Work Plans.

5.5 QUALITY IMPROVEMENT

After an assessment, the team reviews the experience and identifies what went well and what needs improvement in the assessment process. They also consider how the process is supporting EPA's environmental decision-making. The goals for the assessment are revisited. The findings from one assessment of an organization can be used in planning for its next assessment. In the future, the assessment team may decide to concentrate on areas where deficiencies were identified, areas with significant staff turnover between assessments, areas added to the program since the last assessment, or areas that were not previously assessed.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

**Region 12
Juneau, Alaska 99801**

April 15, 2003

Julia Bennett, Commissioner
Alaska Department of Environmental Conservation
410 Willoughby Avenue, Suite 303
Juneau, Alaska 99801-1795

Dear Commissioner Bennett:

This letter confirms the close-out of the assessment of the Alaska Department of Environmental Conservation's quality system conducted by Region 12 during the week of January 27, 2003. Based on our evaluation of your response to the draft assessment report, we have determined that all deficiencies have been resolved. This is reflected in the final assessment report, which is enclosed.

Thank you very much for your cooperation and assistance during the assessment. Please contact me if you have any further questions about the assessment.

Respectfully,

William Shipley
Regional Administrator

Enclosure: Final Assessment Report

cc: Mark Zimmerman, DEC QA Manager

Figure 12. Example Close-Out letter

CHAPTER 6

6.1 REFERENCES

- Adams, N. H., 2000. “*Never Audit Alone-The Case for Audit Teams.*” Presented at the 19th Annual National Conference on Managing Environmental Quality Systems, Albuquerque, NM.
- De Leeuw, E.D., 1992. “*Data Quality in Mail, Telephone and Face-to-Face Surveys.*” TT-Publikaties, ISBN 90-801073-1-X. Amsterdam, Netherlands.
- U.S. Environmental Protection Agency, 2000a. *EPA Order 5360.1.A2: Policy and Program Requirements for the Mandatory Agency-wide Quality System.* Washington, DC.
- U.S. Environmental Protection Agency, 2000b. *EPA Order 5360 A1: EPA Quality Manual for Environmental Programs.* Washington, DC.
- U.S. Environmental Protection Agency, 2001. *EPA Requirements for Quality Management Plans (QA/R-2).* EPA/240/B-01/002. Office of Environmental Information, Washington, DC.
- U.S. Government Accounting Office (GAO). 1991. *Using Structured Interviewing Techniques.* GAO/PEMD-10.1.5. Washington, DC.
- U.S. Government Accounting Office (GAO). 1993. *Developing and Using Questionnaires.* GAO/PEMD-10.1.7. Washington, DC.
- Worthington, J.C., 1998. “Continuous Improvement in Quality Audit Systems.” *Environmental Testing Analysis*, 7(1):23-26.

6.2 SUPPLEMENTAL READING

EPA Documents (http://www.epa.gov/quality/qa_docs.html)

- U.S. Environmental Protection Agency, 1998. *EPA Guidance for Quality Assurance Project Plans (QA/G-5).* EPA/600/R-98/018. Washington, DC.
- U.S. Environmental Protection Agency, 2000. *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9).* EPA/600/R-96/084. Washington, DC.
- U.S. Environmental Protection Agency, 2001. *Guidance for the Data Quality Objectives Process (QA/G-4).* EPA/600/R-96/055. Washington, DC.

- 1249 U.S. Environmental Protection Agency, 2000c. *Guidance on Technical Audits and Related*
1250 *Assessments (QA/G-7)*. EPA/600/R-99/080. Washington, DC.
- 1251 U.S. Environmental Protection Agency, 2001. *EPA Requirements for Quality Assurance Project*
1252 *Plans for Environmental Data Operations (QA/R-5)*. EPA/240/B-01/003. Washington,
1253 DC.
- 1254 U.S. Environmental Protection Agency, 2001. *Guidance for the Preparation of Standard*
1255 *Operating Procedures for Quality-Related Operations (QA/G-6)*. EPA/240/B-01/004.
1256 Washington, DC.
- 1257 **Not available electronically:**
- 1258 U.S. Department of Energy, Office of Environmental Policy & Assistance and U.S. Environmental
1259 Protection Agency, Office of Federal Facilities, undated. *Environmental Management*
1260 *Systems Primer for Federal Facilities*. DOE/EH-0573. Washington, DC.
- 1261 **EPA Regulations (<http://access.gpo.gov/nara/cfr/cfr-table-search.html>)**
- 1262 40 CFR 2, Subpart B, Code of Federal Regulations. *Confidentiality of Business Information*.
- 1263 40 CFR 30, Code of Federal Regulations. *Grants and Agreements with Institutions of Higher*
1264 *Education, Hospitals, and Other Non-Profit Organizations*.
- 1265 40 CFR 31, Code of Federal Regulations. *Uniform Administrative Requirements for Grants and*
1266 *Cooperative Agreements to State and Local Governments*.
- 1267 40 CFR 35, Code of Federal Regulations. *State and Local Assistance*.
- 1268 **International Organization for Standardization (ISO) Documents (<http://www.iso.ch>)**
- 1269 *Guidelines for Auditing Quality Systems-Auditing*, ISO Standard 10011-1-1994.
- 1270 *Guidelines for Auditing Quality Systems-Management of Audit Programs*, ISO Standard 10011-
1271 3-1994.
- 1272 *Guidelines for Auditing Quality Systems-Qualification Criteria for Quality System Auditors*, ISO
1273 Standard 10011-2-1994.
- 1274 **American Society for Quality (ASQ) Publications (<http://www.qualitypress.asq.org> and**
1275 **<http://www.asq.org>)**

- 1276 American Society for Quality, 1987. *How to Plan an Audit*, ASQC Quality Audit Technical
1277 Committee, C.B. Robinson, ed. American Society for Quality, Milwaukee, WI.
- 1278 American Society for Quality, 1994. *Specifications and Guidelines for Quality Systems for*
1279 *Environmental Data Collection and Environmental Technology Programs*, ANSI/ASQC
1280 E4-1994. American Society for Quality, Milwaukee, WI.
- 1281 American Society for Quality Standards Committee, 1994. *American National Standard.*
1282 *Guidelines for Auditing Quality Systems*. ANSI/ISO/ASQC Q10011-1-1994, Q10011-2-
1283 1994, Q10011-3-1994. American Society for Quality, Milwaukee, WI.
- 1284 Arter, D.R., 1994. *Quality Audits for Improved Performance, Second Edition*. American Society
1285 for Quality, Milwaukee, WI.
- 1286 Beeler, DeWitt, 1998. "Internal Auditing: The Big Lies." *Quality Progress*, 31(5):73-78.
- 1287 Mills, C.A., 1989. *The Quality Audit: A Management Evaluation Tool*. American Society for
1288 Quality, Milwaukee, WI.
- 1289 Sayle, A.J., 1997. *Management Audits. The Assessment of Quality Management Systems, Third*
1290 *Edition*. American Society for Quality, Milwaukee, WI.
- 1291 Smith, J.L., 2000. *The Quality Audit Handbook, Second Edition*. ASQ Quality Audit Division, J.P.
1292 Russell, ed. ASQ Quality Press, Milwaukee, WI.

GLOSSARY

assessee - the organization being assessed.

assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements.

assessment checklist - a document for systematically recording objective evidence from interviews. It is useful as a means to obtain information that has not been documented by the assessee. It consists of a series of specific questions about the quality system. When completed, the assessment checklist demonstrates that the assessment was conducted, that it was conducted in an orderly and complete manner, and that all relevant aspects of the quality system were addressed during the assessment.

assessment criteria - objective and written reference standards to which the assessed quality system's characteristics are compared. These documents may be external requirements coming from outside the assessee as well as the assessee's own requirements and quality system planning documents.

assessment of a quality system - a process for assessing an organization's practices as they relate to its quality system. The focus of the assessment process is on the quality system rather than the quality of data to support an individual decision. Assessments are designed to assess the organization's quality system and to provide a relatively unbiased and objective source of feedback about the quality system. The assessment seeks to determine if a quality system is implemented and is operating within an organization in the manner prescribed by the approved Quality Management Plan and consistent with current requirements.

assessment plan - a written document prepared by the assessment team under the direction of the assessment team leader. It includes the authority and assessment criteria for the assessment, the purpose and scope of the assessment, and a description of organizations that will be visited during the assessment. The plan includes details, such as a schedule of assessment activities, specific personnel (or job positions) to be interviewed, and specific files and documentation that will be reviewed during the assessment.

assessment team leader - the person responsible for all phases of the assessment. The assessment team leader has management ability and experience and is given authority to make final decisions regarding the conduct of the assessment and any assessment findings.

assessor - the person or team of people who perform the assessment. The assessor can be either internal (part of the organization being assessed) or external.

1329 **audit** - a systematic and independent examination to determine whether activities and related results
1330 comply with planned arrangements and whether these arrangements are implemented effectively and are
1331 suitable to achieve objectives.

1332 **authorizing entity** - whomever authorizes the assessment and has the authority to do so. This is often
1333 the individual responsible for the quality system that is being assessed.

1334 **corrective action** - action taken to eliminate the causes of an existing nonconformance, deficiency, or
1335 other undesirable situation in order to prevent recurrence.

1336 **deficiency** - a negative assessment finding (i.e., a nonconformance) that renders the quality of an item
1337 or activity unacceptable or indeterminate; nonfulfillment of a specification or standard.

1338 **document** - any compilation of information that describes, defines, specifies, reports, certifies, requires,
1339 or provides data or results pertaining to environmental programs.

1340 **documentation** - comprises documents and records.

1341 **environmental data** - any measurements or information that describe environmental processes,
1342 locations, or conditions; ecological or health effects and consequences; or the performance of
1343 environmental technology. For EPA, environmental data include information collected directly from
1344 measurements, produced from models, and compiled from other sources such as data bases or the
1345 literature.

1346 **environmental data operation** - work performed to obtain, use, or report information pertaining to
1347 environmental processes and conditions.

1348 **external assessment** - see management independent assessment.

1349 **extramural agreement** - a legal agreement between EPA and an organization outside EPA for items
1350 or services to be provided. Such agreements include contracts, work assignments, delivery orders,
1351 task orders, cooperative agreements, research grants, state and local grants, and EPA-funded
1352 interagency agreements.

1353 **financial assistance** - the process by which funds are provided by one organization (usually the
1354 government) to another organization for the purpose of performing work or furnishing services or items.
1355 Financial assistance mechanisms include grants, cooperative agreements, and government interagency
1356 agreements.

1357 **finding** - an assessment conclusion that identifies a condition having a significant effect on an item or
1358 activity. An assessment finding may be positive or negative, and is normally accompanied by specific
1359 examples of the observed condition.

1360 **graded approach** - the process of applying managerial controls to an item or work according to the
1361 intended use of the results and the degree of confidence needed in the quality of the results.

1362 **independence** - freedom from bias and external influences that could affect the assessor's objectivity.

1363 **independent assessment** - see management independent assessment.

1364 **internal assessment** - see management self-assessment.

1365 **management** - those individuals directly responsible and accountable for planning, implementing, and
1366 assessing.

1367 **management independent assessment** - the qualitative evaluation of a particular program operation
1368 and/or organization(s) by those immediately responsible for overseeing and/or performing the work to
1369 establish whether the prevailing management structure, policies, practices, and procedures are adequate
1370 for ensuring that the type and quality of results needed are obtained.

1371 **management self-assessment** - the qualitative evaluation of a particular program operation and/or
1372 organization(s) by someone other than the group performing the work (either internal or external to the
1373 organization) to establish whether the prevailing management structure, policies, practices, and
1374 procedures are adequate for ensuring that the type and quality of results needed are obtained.

1375 **management system audit** - see management independent assessment.

1376 **management system review** - an assessment of a developing quality system, including technical
1377 assistance in developing the quality system, as well as evaluation of the quality system.

1378 **nonconformance** - a negative assessment finding of a deviation from standards, requirements, and
1379 documented practices, which may be either a deficiency or a weakness.

1380 **noteworthy practice or condition** - a positive assessment finding; a strength.

1381 **observation** - an assessment finding that identifies a neutral condition that does not represent a
1382 significant impact (either positive or negative) on the quality of an item or activity, based on
1383 observations, measurements, or tests that can be verified.

1384 **organization** - a company, corporation, firm, enterprise, or institution, or part thereof, whether
1385 incorporated or not, public or private, that has its own functions and administration. In the context of
1386 EPA Order 5360.1, an EPA organization is an office, region, national center, or laboratory.
1387 **procedure** - written instructions for performing a tasks, not the actions themselves.

1388 **quality assurance** - an integrated system of management activities involving planning, implementation,
1389 documentation, assessment, reporting, and quality improvement to ensure that a process, item, or
1390 service is of the type and quality needed and expected by the customer.

1391 **quality control** - the overall system of technical activities that measures the attributes and performance
1392 of a process, item, or service against defined standards to verify that they meet the stated requirements
1393 established by the customer; operational techniques and activities that are used to fulfill requirements for
1394 quality.

1395 **Quality Management Plan** - a document that describes a quality system in terms of the organizational
1396 structure, policy and procedures, functional responsibilities of management and staff, lines of authority,
1397 and required interfaces for those planning, implementing, documenting, and assessing all activities
1398 conducted.

1399 **quality procedures** - written instructions for planning, implementing, documenting, or assessing
1400 specific activities associated with the quality system.

1401 **quality system** - a structured and documented management system describing the policies, objectives,
1402 principles, organizational authority, responsibilities, accountability, and implementation plan of an
1403 organization for ensuring quality in its work processes, products (items), and services. The quality
1404 system provides the framework for planning, implementing, documenting, and assessing work
1405 performed by the organization and for carrying out required QA and QC activities.

1406 **record** - a completed document that provides objective evidence of an item or process. Records may
1407 include photographs, drawings, magnetic tape, and other data recording media.

1408 **self assessment** - see management self-assessment.

1409 **strength** - a positive assessment finding; a strong attribute or inherent asset.

1410 **weakness** - a negative assessment finding (i.e., a nonconformance) that does not necessarily result in
1411 unacceptable data.

1412 **working papers** - documents such as checklists that are used to record information during the
1413 assessment.

1414

APPENDIX A

1415

GUIDANCE FOR THE ASSESSEE

1416

This appendix provides guidance for those being assessed, who may not be interested in all of the details provided in the main document.

1417

1418

What is a quality system?

1419

A quality system is the set of management policies and procedures and related technical procedures that an organization has developed and documented to ensure that its products and services (e.g., environmental data collection, environmental technology) attain some specified quality objectives. The top management of the organization initiated the development of these policies and procedures and now stands behind them as the expected way of doing things in the organization. The quality system may have been developed in response to internal initiatives or external requirements.

1420

1421

1422

1423

1424

1425

What is an assessment of a quality system?

1426

An assessment of a quality system is a systematic, independent, and documented examination that uses specified assessment criteria to answer one or more of the following questions about an organization's quality system:

1427

1428

1429

- If an organization is developing a quality system, what QA activities remain to be implemented and what technical assistance by the assessors will promote the development and implementation of this quality system?
- Is the organization's quality system documented and fully implemented?
- Does the organization understand external quality requirements?
- Does the quality system comply with external quality requirements?
- Do the activities that are being performed by the organization comply with its quality system documentation, particularly the Quality Management Plan?
- Are the quality system procedures implemented effectively?
- Does the quality system support environmental decision making with processes that ensure that data are sufficient in quantity and quality appropriate for their intended purpose?

1430

1431

1432

1433

1434

1435

1436

1437

1438

1439

1440

1441

An assessment of a quality system has a different focus from a technical systems audit, which determines whether the organization's technical procedures are being followed and whether they generate work products of a specified quality. Rather, it looks at the management policy and procedures that are used to plan, implement, assess, and correct the technical activities.

1442

1443

1444

1445 The assessment strives to be objective and is performed by assessors who are independent of
1446 doing or managing the technical activities. The assessors have no vested interest in the quality system
1447 being assessed.

1448 **Why is an assessment needed?**

1449 EPA organizations are required to perform assessments of their quality systems at least
1450 annually. EPA regulations governing extramural agreements require assessment of extramural
1451 organizations by EPA. Extramural organizations are required to perform periodic internal assessments
1452 of their own quality systems. An extramural organization's use of assessments is described in its Quality
1453 Management Plan.

1454 One purpose of an assessment is to improve the assessee's quality system, whether it is mature
1455 or developing. Another purpose of an assessment is to provide valid feedback to management on the
1456 adequacy, implementation, and effectiveness of the quality system.

1457 **Who are the assessors? Who do they represent?**

1458 Assessors may either be from part of the organization being assessed (internal) or from outside
1459 the organization being assessed (external). They are trained for their assessing responsibilities and have
1460 reviewed relevant materials to prepare for the particular assessment. They represent the authorizing
1461 entity; that is, the organization that authorized the assessment. Often the authorizing entity is the
1462 individual responsible for the quality system in an organization.

1463 **What are the criteria for the assessment?**

1464 Assessment criteria are objective and written reference standards to which the assessed quality
1465 system's characteristics are compared. These documents may be external requirements that are
1466 applicable to the assessee as well as the assessee's own requirements and quality system planning
1467 documents. Assessment criteria are agreed upon by the assessors, the authorizing entity, and the
1468 assessee before the assessment begins. Generally, the following documents outline the assessment
1469 criteria for quality systems for work performed by or for EPA:

- 1470 • Order 5360.1 A2
- 1471 • EPA's Quality Manual
- 1472 • EPA requirements for Quality Management Plans
- 1473 • ANSI/ASQC specifications and guidelines for quality systems
- 1474 • the assessee's Quality Management Plan
- 1475 • the assessee's reports (e.g., quarterly progress reports or Quality Assurance Annual
- 1476 Report and Work Plan)
- 1477 • QA and QC requirements in regulations.

1478 **What can I expect to happen during an assessment?**

1479 In addition to determining compliance with quality system requirements, an assessment is an
1480 opportunity for the assessed organization to obtain independent feedback about the suitability and
1481 effectiveness of its own quality system. An assessment is an opportunity for recognition of the
1482 assessee's commendable practices and a chance to "showcase their talents." Assessments also
1483 provide an opportunity for two-way communication between the assessee and the assessment team.
1484 Assesseees are encouraged to keep a spirit of cooperation through the assessment process.
1485 Assessments emphasize quality improvement.

1486 **What does "no surprises" mean?**

1487 Assessments will be performed in an open and collegial manner, and every effort will be made
1488 to avoid surprises. The "no surprises" approach means that the assessee will be made fully aware of
1489 the scope of the assessment and how the findings will be used before the assessment takes place. The
1490 assessee will be invited to contribute to assessment planning to help assure that they understand what
1491 will be done. Moreover, the draft report will not introduce any issues that were not discussed at the
1492 closing meeting or in later discussions.

1493 **What logistical arrangements are required for an assessment?**

1494 The assessment team will make initial contact with the assessee to announce its intention to
1495 conduct an assessment, discuss possible dates, describe the criteria and scope of the assessment,
1496 request necessary documents, and reserve space for document reviews and interviews. The assessee is
1497 candid in the discussion about the personnel and program schedules so that the assessment does not
1498 occur at a time when the needed staff members are unavailable. The assessee is encouraged to
1499 respond to requests for information in a timely manner because making information available before the
1500 assessment will reduce disruptions during the assessment. The assessee designates a point of contact,
1501 usually the organization's QA Manager, for the assessment. The assessee informs the assessment team
1502 of any necessary procedures for admittance to the assessment site and any safety requirements. If the
1503 assessment will involve CBI, the assessee notifies the assessment team leader so that the CBI process
1504 can be initiated. The assessee may also provide information about travel logistics and local
1505 accommodations.

1506 The assessee arranges for appropriate personnel to be present at the opening and closing
1507 meetings and available for interviews. Assessment interviews generally last for one hour. The assessee
1508 has adequate space available for the meetings, interviews, and document reviews. While some
1509 documents, records, and files will be sent to the assessment team ahead of time, others will need to be
1510 readily accessible during the on-site portion of the assessment. It may be appropriate for the
1511 assessee's QA Manager or other designated point of contact to brief the assessee's senior management
1512 prior to the on-site assessment.

The assessee will want to inform their personnel of the impending assessment and arrange for their participation in the assessment. Ideally, the assessee conveys a positive attitude about the assessment and the assessors. Staff members understand that the quality system, not the interviewees, is being assessed. The assessee may want to perform self-assessments in preparation for an independent assessment. These self-assessments will keep the staff aware of assessment procedures and encourage maintenance of necessary documents and records.

Occasionally, an unexpected event occurs, and there is a sudden change of plans. The assessment agenda may require rearrangement, or there may be a substitution of personnel resulting from illness. The assessment team is notified of these changes as soon as possible.

What will the assessment notification and assessment plan contain?

The notification memorandum will identify the assessment team members and their affiliations and define the assessment scope, the assessment criteria, assessment authority, and a tentative schedule. The assessment plan will specify the authority for the assessment, the assessment criteria, and the purpose and scope of the assessment. Details such as a schedule of assessment activities, specific personnel to be interviewed, and documentation to be reviewed will be included in the assessment plan. The assessment plan will clearly state the rules for dissemination of assessment findings and confidentiality for the particular assessment. Ideally, the assessee receives written notification and the formal assessment plan at least two weeks before the assessment or in enough time to schedule the interviews and to collect the documents to be reviewed.

Will the assessment cover only the points specified in the assessment plan?

The assessment plan provides a comprehensive approach to the assessment, based on the assessment team's understanding from reviewing relevant quality system documents before the assessment. During the assessment, however, the assessment team may realize that there are other aspects of the quality system that require additional attention. This may require minor changes to the assessment plan, which will be documented by the assessment team and discussed with the assessee's management. If the organization's quality system is not fully implemented, the assessment may be focused on promoting its development, rather than listing its deficiencies.

What can I expect to occur during the opening meeting? What do we talk about during the meeting? Who is coming to the meeting from the assessor side?

The opening meeting is generally attended by the assessee's QA Manager, senior staff, other staff as appropriate, and the assessment team. At the opening meeting, all assessee personnel and the assessment team introduce themselves. The assessment team will briefly discuss the assessment scope and criteria. The assessee is prepared to ask any questions that they have and to respond to questions from the assessment team. Although an assessee may feel anxious about the assessment, the

assessment is approached as something that will benefit the assessed organization. The assessors can look at the quality system objectively and provide assistance to the organization based on experiences from other assessments. This approach helps to ensure that the assessment will promote improvements in the quality system.

What will happen during the assessment?

During the assessment, the staff will be interviewed as specified in the assessment plan. The quality system is the focus of the assessment, rather than the individuals in the organization. There is no need for the interviewees to feel that their job performance is being judged. Management can set an example for the staff by projecting a positive attitude toward the assessment and the assessors.

Staff cooperate with the assessment team during the assessment. They respond appropriately and fully to the assessor's questions. Their responses remain focused on the topic of the question and do not include tangential material. It is possible that an assessor may misunderstand a particular response. In that event, a respondent attempts to correct any apparent errors in the assessor's understanding. An appropriate question to the assessor may help to clarify the assessor's understanding. Remember that the interviewees are more familiar with their quality system than the assessor, who is attempting to cover a lot of material in a short time.

Documents and records, as specified in the assessment plan, will be reviewed to verify evidence of compliance with the quality system requirements. Files are examined to find relevant data and records and to confirm information collected during interviews.

During the assessment, the organization's quality manager can act as liaison with the assessment team and can address any logistical needs that arise. If needed, the quality manager can provide an escort for the assessment team while they are on site.

What can I expect to occur during the closing meeting?

The closing meeting is generally attended by the same staff that attended the opening meeting. At this meeting, the assessment team leader discusses the team's findings. If contrary evidence exists of which the assessors are unaware, this is the time to present it. If the assessors have misunderstood anything, this is an opportunity to offer correction. If the assessors have requested information during the assessment that was not immediately available, the assessee notes this request and provides the information on a realistic timetable. If the information will not be available when needed by the assessors, the assessee states candidly why it is not available.

1579 **How will the assessment be reported?**

1580 Many assessment organizations prepare a written draft assessment report for review by the
1581 assessee, while others present an oral report at the end of the on-site portion of the assessment in lieu of
1582 a written draft report. In either case, the assessment team will prepare a written final report, which
1583 incorporates any relevant comments from the assessee when appropriate, corrects any identified factual
1584 errors, and resolves any disputes if possible. After final approval for the report is received from the
1585 authorizing entity, it is distributed as previously agreed in the assessment plan.

1586 A written draft report, when that approach is used, provides the assessee with an opportunity
1587 to comment on the report before it is finalized, but this approach does require additional time. The
1588 assessment team will send the draft report to the assessee for review after it has been reviewed by the
1589 assessing organization and authorizing entity. This is an opportunity for the assessee to correct any
1590 factual errors in the report. The assessee's review can be thorough, but timely. If the assessee does
1591 not respond in a timely fashion, the assessment team leader will contact the assessee QA Manager or
1592 designated point of contact. The assessee will complete the corrective action plan (if one is attached to
1593 the draft report) and include the planned corrective action, responsible party, and due date. The
1594 confidentiality and dissemination of assessment findings and reports have been decided and agreed to
1595 during the assessment planning process, and the agreement is documented in the assessment plan.

1596 For some assessments, the assessment criteria and issues may be so straightforward as to
1597 permit concluding the assessment on-site with a presentation of a streamlined report, which does not
1598 need additional explanation. This method, like more conventional reporting, would warrant up-front
1599 agreement with both the authorizing entity and the assessee.

1600 **How do I address any problems with the assessment findings? What happens if I disagree**
1601 **with them?**

1602 Any disputes over the assessment findings and the draft report are resolved at the lowest
1603 administrative level possible and in accordance with the dispute resolution process for the assessment
1604 program. It may be necessary for the assessment program manager or the authorizing entity to play a
1605 role in dispute resolution. If any serious problems are noted by the assessee during the assessment,
1606 such as inappropriate assessor behavior or release of confidential information, the assessee notifies the
1607 management of the assessing organization.

1608
1609 **What do I do after the assessment?**

1610 In addition to reviewing the assessment report, the assessee is responsible for developing,
1611 implementing, following up on, and tracking corrective actions. The assessment team may provide
1612 assistance and check with the assessee to follow up, but the assessee is responsible for their quality
1613 system and any improvements to it.

1614 **How will the assessment findings be distributed? What about confidentiality?**

1615 Procedures for distribution and confidentiality of the assessment report are agreed to ahead of
1616 time by the assessment team, the assessee, and the authorizing entity and are documented in the
1617 assessment plan.

APPENDIX B

INTERVIEWING SKILLS

Communication skills can be easily overlooked or underappreciated, but in conducting assessments they may be as important as technical skills. The goal of the assessment interviews is to generate data that are reliable, unambiguous, and of the type, quality, and quantity needed to meet the objectives of the assessment. During an assessment, interviews will help the assessment team understand if, how, and to what extent the policies and procedures have been communicated, understood, and implemented. Interviews are supplemented by documentation reviews, which aid in verifying the existence, implementation, and effectiveness of the actual policies, processes, and procedures.

Barriers to effective communication include:

- personal or collective biases toward particular people, ideas, or procedures
- lack of feedback
- poor listening skills
- misunderstanding of nonverbal clues
- distractions
- personality conflicts.

Nonverbal behaviors, such as facial expressions, posture, tone, inflection, position in the room, gestures, and silence, all make a difference in the interviewee's perception so it is important that the interviewer be aware of his or her own nonverbal behavior and the messages that are being sent to the interviewee. The interviewer will also want to observe the nonverbal behaviors of the interviewee, but only within the context of the interview. It is important to neither dismiss nor overinterpret any nonverbal communication and to note that interpretation of body language is not objective evidence.

Active listening is an important part of interviewing. Compared to simply listening, active listening requires a great deal of effort. Active listening involves verbally responding, with the listener mirroring back the speaker's message to further clarify understanding. This lessens the possibility of false assumptions and leads to more accurate interview notes. Active listening has physical, mental, and motivational aspects. The physical aspects may include making eye contact with the interviewee and nodding to indicate understanding. The mental aspect requires that the interviewer pay attention to what the interviewee is saying. Examples of the motivational aspects of active listening include responses such as "I understand" and "That's interesting, could you elaborate further?" An important aspect of active listening is to stop talking and to position yourself to direct your attention to what the speaker is saying.

Appropriate feedback during active listening can include:

- 1655 • neutral (“I see. Please go on . . .”)
- 1656 • clarifying (“I’m not sure I understand . . .”)
- 1657 • paraphrasing (“So in other words, you are saying that . . .”)
- 1658 • impression checking (“I get the impression that . . .”)
- 1659 • summarizing (“Okay. To sum up . . .”).

1660

1661 Feedback can be very important, especially if you are receiving nonverbal cues that do not match the
1662 verbal message that you hear.

1663 Interviews generally consist of three steps: opening, questions and comments, and summation
1664 and closing. The opening step will include introductions, small talk, explanations (for instance, an
1665 explanation of the assessment objective), and agreement to continue with the interview. The point of
1666 the opening step is to help the interviewee feel at ease and to keep the process a “no surprises” one.
1667 During the interview process, the interviewer ensures that the interviewee understands the meaning of
1668 the questions as intended. This may require additional explanation or checking for understanding. After
1669 asking all of the interview questions, the interviewer will summarize the main issues and close the
1670 meeting, allowing the interviewee to ask any final questions, ask for clarification of any points, and make
1671 any closing statement

1672 During the planning step of the assessment, as described in Chapter 3, careful consideration of
1673 the types of information that is needed leads to a decision about the types of questions to ask. Four
1674 types of questions, which may be appropriate for use during an assessment, are summarized in Table
1675 B-1.

1676 **Table B-1. Types of Questions**

1677 Type	Description	Example
1678 Open-ended	Designed to prompt the speaker to provide detailed information	“What is the role of technical experts in planning your office’s projects?”
1679 Directive	Leads the speaker to one of two choices	“If you had to choose a method, would you choose the EPA method or another one?”
1680 Leading	Hints at the answer the interviewer is seeking	“Working with too little QA support doesn’t bother you, does it?”
1681 Hypothetical	Questions that place the interviewee in a hypothetical situation	“If you were in charge of the support contract, how would you change the requirements for QA?”

No matter which type of question is selected, the questions used in the interview phase of an assessment are intended to be simple and understandable, brief, thought-provoking, limited in scope, and unbiased. It is important to remember that the way a question is phrased will greatly influence how it is received by the interviewee.

When possible, given the staffing, time, and other resource constraints, many assessment programs prefer to have two assessors participate in all interviews. One person can ask questions and lead the discussion including thinking of follow-up questions, while the other assessor can listen more carefully and record responses. The two assessors can switch between these roles. They can ask questions in a “tag team” alternation in which the listener for one question is preparing to pose the next question to the interviewee. It is important to remember that the goal is not to complete the checklist, but to use the checklist to obtain the desired information. The interviewee is allowed time to reflect and answer the question fully.

There are a variety of difficult interview situations that the assessor might encounter. One of these is an apprehensive interviewee. The characteristics of this interviewee may include an unsteady voice or a “frozen” look. It is human nature to be apprehensive in an assessment situation, which is why it is important to include introductions and small talk in the interviews. This behavior does not particularly mean that the person “has something to hide” and usually the interviewee will become helpful after their apprehensions have passed.

Another potential problem is a defensive interviewee. This person may give apprehensive responses, short comments, and may seem concerned about impressions. It is important that the interviewer recognize his or her effect on the interviewee.

Sometimes, the interviewee may be too talkative, with many digressions and long-winded responses. After the first digression, wait and allow the interviewee to talk for a while before rephrasing the question and trying again. After the second digression, interrupt and clarify. While the interview is careful to not harm trust or risk any established rapport, no further digressions is allowed.

Another potential problem can be a disorganized interviewee. This person might seem easily confused or distracted. The first step is to determine if the interviewee is disorganized by nature or if he or she is confused by the topic or the way the question is asked. If the latter is the case, further explanation or rewording of the question may resolve the problem.

An arrogant interviewee is characterized by short and sharp answers, acting too busy, and glib or cute responses. This person may be motivated by fear or nervousness. It is important that the interviewer keep control of his or her ego and not lose control of the situation. The goal of the interview is to obtain quality information.

1717 A hostile interviewee may withhold information or provide worthless information. The hostile
1718 interviewee may show open fear or anger or may seem impatient. If possible, the interviewer
1719 determines the reason for the hostility and if there are “hidden objectives” on the interviewee’s part. If
1720 a particular topic seems to evoke hostile behavior, the interviewer leaves this topic until rapport has
1721 been reestablished. The interviewer may decide to end the interview if the hostility does not end, after
1722 consulting with the assessment team leader, if possible.

1723

APPENDIX C

1724

EXAMPLE ASSESSMENT ISSUES WITH INTERVIEW QUESTIONS FOR DEVELOPING AND MATURE QUALITY SYSTEMS

1725

1726

The following six sets of example interview questions are representative of the questions that might be asked about assessment issues. The sets alternate between questions that are appropriate for a developing quality system and those that are appropriate for a more fully implemented and documented (“mature”) quality system. Because more information about mature quality systems is available to the assessor before the interviews, the questions about these quality systems reflect more of the need to confirm existing quality processes rather than to gather information about them. These questions are tailored for three example quality system roles: senior manager/QA staff supervisor; as manager/staff; and field sampler. It is expected that an appropriate number and appropriate types of personnel would be selected to assure adequate coverage of the assessment issues.

1727

1728

1729

1730

1731

1732

1733

1734

A. Senior Manager/QA Staff Supervisor for a Developing Quality System
Interviewee's Background and Role in the Quality System

- Verify the interviewee's name, title, and organizational unit, if necessary. Note the date and time of the interview.
- How you ensure the quality of environmental data collected and used by your organization?

Quality System Context, Resources and Documentation Status

- What quality system functions, for example, project planning, oversight, and record keeping, are critical to your organization's data collection and use?
- What resources have been allocated for the development of the quality system?
- Where is the QA Manager/staff in your organizational structure?
- What functions are being performed by your organization's QA Manager/staff?
- What is the current status of the documentation of the quality system?

Training Policy and Resources

- Describe your background in QA principles and procedures.
- How do you assure that your staff is familiar with your quality system?
- How are the needs of the staff for QA training assessed and met?

Systematic Project Planning and Documentation

- Describe your organization's systematic process for project planning.
- Who participates in the planning process?
- How is the planning process documented?
- What is the process for review and approval of QA Project Plans?

Additional question areas could include project implementation and oversight, project- and system-level assessments, etc., based on the assessment objectives and issues.

1759 **B. Senior Manager/QA Staff Supervisor for a Mature Quality System**
1760 **Interviewee's Background and Role in the Quality System**

- 1761 • Verify the interviewee's name, title, and organizational unit, if necessary. Note the
1762 date and time of the interview.
1763 • What is your role in the quality system?

1764 **Quality System Communications and Resources**

- 1765 • How (and how often) do you communicate with the QA Manager/staff?
1766 • What input on the quality system do you receive?
1767 • How is the adequacy of QA resources assessed?
1768 • What input from the QA staff is considered in resource planning?

1769 **Quality System Assessment**

- 1770 • How are internal assessments planned and scheduled?
1771 • How are assessments reported?
1772 • Who develops and implements corrective actions in response to assessment findings?
1773 • How are disputes handled?
1774 • How are corrective actions tracked to completion?

1775 **Quality Improvement**

- 1776 • How do you assure ongoing improvement of your quality system?

1777 **Additional question areas could include oversight of assistance agreement holders, and**
1778 **contractors, resource issues concerning compliance, or other issues within the scope of the**
1779 **senior manager's direct responsibilities.**

C. QA Manager/Staff in a Developing Quality System

Interviewee's Background and Role in the Quality System

- Verify the interviewee's name, title, and organizational unit, if necessary. Note the date and time of the interview.
- Describe your training and experience in quality assurance.
- What additional QA training would be helpful to you?
- What is your role in the organization's planning for, collecting, and using environmental data?
- To whom do you report in the organization?
- What portion of your job is in quality assurance?

Quality System Implementation Status

- What is the current status of the development of the quality system?
- What functions do the quality system now perform in the data collection and use process?
- What quality system functions are critical to the data collection and use process?
- What QA support do you provide to managers/decision makers and to staff? What additional QA support are you developing for them?
- What is your role in writing the Quality Management Plan?
- How does the organization's management support the development of the quality system?
- What resources have been allocated for the development of the quality system?
- What external support, if any, would aid the development of the quality system?

Training

- How are the training needs of your organization assessed?
- What QA training is provided currently to project officers and staff?
- What additional QA training for project officers and staff are you developing?
- What additional QA training would you like to see made available?
- What is the organization's policy regarding training the staff in QA principles and procedures?

Systematic Planning

- Describe the process used in research program and project planning.
- How does the organization address the needs of data users and decision makers during planning?
- What technical support, tools, or expertise (e.g., statistical, field, laboratory) is available or needed for planners?

Additional question areas could include project implementation and oversight, project- and system-level assessments, record keeping, etc., based on the assessment objectives and issues.

D. Quality Assurance Manager/Staff in a Mature Quality System

Interviewee's Background and Role in the Quality System

- Verify the interviewee's name, title, and organizational unit, if necessary. Note the date and time of the interview.
- Describe your training and experience in QA.

QA Line of Reporting and Independence

- To whom do you report on QA matters in the organization and who appraises your performance?
- Describe your current position, especially any duties that relate to environmental data collection or use.
- What portion of your job is devoted to QA duties?
- How is your QA responsibility reflected in your performance agreement?

Training and Communications

- How and how often are the needs of the staff for QA training evaluated?
- How is QA training being tracked?
- How are the QA training needs satisfied?
- How are new or changes to QA policies and procedures disseminated to the organization?

Quality System Assessments

- Describe the management support for, the process for, and the frequency of internal assessments of the quality system.
- How have the assessments improved the quality system?
- How are corrective actions tracked?
- Have there been instances in which the quality of environmental data has been challenged? If so, what was done to investigate the quality of the data and to respond to the challenge? What was learned about the quality system?

It is expected that documentation would be produced and examined to substantiate responses where appropriate.

Additional question areas could include quality system documentation, project planning, implementation and oversight, etc., based on the assessment objectives and issues.

1848

E. Field Sampler in a Developing Quality System

1849

Interviewee's Background and Role in the Quality System

1850

- Verify interviewee's name, title, and organizational unit, if necessary. Note the date and time of the interview.

1851

1852

- What is your role in the process of planning for, collecting, and using environmental data?

1853

1854

- What training have you received in QA principles and procedures?

1855

- What additional QA training would be helpful?

1856

Quality System Support

1857

- What support is provided currently by your organization's QA Manager/staff?

1858

- How can your organization's QA Manager/staff help you further?

1859

Quality System Documentation

1860

- How do you plan field sampling?

1861

- What QA and QC activities in your field sampling are documented? Explain any process for writing, reviewing, approving, modifying and controlling the version of these documents.

1862

1863

1864

Additional question areas could include oversight, record keeping, etc., based on the assessment objectives and issues.

1865

F. Field Sampler in a Mature Quality System

Interviewee's Background and Role in Quality System

- Verify the interviewee's name, title, and organizational unit, if necessary. Note the date and time of the interview.

Training and Communications

- What QA training have you received?
- How are your training needs assessed and satisfied?
- Where and how are training records kept?
- How do you receive updates to or new QA policies and procedures?
- Describe your access to and/or support from QA staff.

Quality System Documentation and Record Keeping

- Describe your role in developing and implementing QA Project Plans or standard operating procedures for field sampling.
- What is the process for review and approval and/or changes?
- What other QA documentation do you use (e.g. field notebooks, chain-of-custody forms, etc.)?
- What is the process for review and approval and/or changes?
- What is the process for record keeping of these documents during a project and after completion?

Implementation and Oversight

- How do you get instructions and training for field sampling for a new project?
- What QC checks are done as part of field sampling?
- How and by whom is the information used?
- What type of oversight is done of your field work?
- Who decides what will be done and when?
- Who oversees the field operation and what is done with the information?

Assessments

- Have there been assessments of the field sampling program? When was the most recent assessment? Who did the assessment?

1895

APPENDIX D

1896

EXAMPLE CHECKLIST

1897

Assessment of a Quality System

1898

Interviewee: _____ **Job Category:**

1899

1900

Interview Date: _____ **Time** _____ **Organization:**

1901

1902

Assessor: _____ **Assessing Organization:**

1903

	Source of Assessment Criteria in QMP	
Issues and Questions		Response/Comments
I. Management and Organization		
A. How is management's commitment to the quality system demonstrated?		
B. How are the quality policies that describe the organization's attitude towards quality defined and documented?		
C. How is the structure that management will need to manage the quality system defined and documented?		
D. How are the procedures that program managers and supervisors can use to review the effectiveness of the quality system defined and documented?		
E. How do you oversee the quality system?		
F. How do you document identification of verification requirements and provision of adequate resources including trained personnel for all verification activities?		
G. How do you ensure that quality assurance (QA) activities are included in employees' job descriptions?		
II. Quality System Components		
A. What is the status of development of your quality system and a manual that describes it?		

1904

1905

1906

1907

1908

1909

1910

1911

1912

1913

1914

1915

1916

1917

1918

1919

1920

1921

1922

1923

1924

1925

1926

1927

1928

1929

1930

Assessment of a Quality System

Interviewee: _____ **Job Category:** _____

Interview Date: _____ **Time** _____ **Organization:** _____

Assessor: _____ **Assessing Organization:** _____

	Issues and Questions	Source of Assessment Criteria in QMP	Response/Comments
1931	B. How do implemented quality system		
1932	procedures compare to the quality		
1933	policy?		
1934	C. Describe the preparation, review, and		
1935	approval process of the Quality		
1936	Management Plan (QMP). What was		
1937	your role in this process?		
1938	D. Describe how you developed, designed,		
1939	and documented QA Project Plans.		
1940	E. How do you ensure that your QA Project		
1941	Plans are submitted prior to initiation of		
1942	any data collection, to EPA for review		
1943	and approval?		
1944	F. How do you ensure that the standard		
1945	operating procedures (SOPs) are		
1946	consistent with the quality elements of		
1947	the activities and operational		
1948	requirements?		
1949	G. How do you communicate the QMP roles		
1950	and responsibilities to employees and		
1951	supervisors?		
1952	H. How do you ensure that assigned QA		
1953	responsibilities are understood and		
1954	implemented?		
1955	I. Who has approved the QMP?		
1956	J. How do you conduct periodic		
1957	assessments of programs' quality		
1958	systems to assure compliance with U.S.		
1959	EPA requirements?		
1960	K. How do you ensure that administration		
1961	directors, program managers, and quality		
1962	coordinators address all areas of concern		
1963	in the report of the self-assessment?		

Assessment of a Quality System

Interviewee: _____ **Job Category:** _____

Interview Date: _____ **Time** _____ **Organization:** _____

Assessor: _____ **Assessing Organization:** _____

	Issues and Questions	Source of Assessment Criteria in QMP	Response/Comments
1964	L. What have you submitted as a Quality Assurance Annual Report and Work Plan?		
1965			
1966			
1967	M. How do you ensure that administration directors, program managers, and quality coordinators approved of the annual report?		
1968			
1969			
1970			
1971	N. Please describe the preparation, review, and internal approval process for the self-assessment.		
1972			
1973			
1974	O. Have you implemented the following financial reports as required in the QMP:		
1975			
1976	1. Financial Reconciliation (Control) report or the Undrawn Analysis Report?		
1977			
1978			
1979	2. Federal Grant Inventory Report (FGIR)?		
1980			
1981	P. How do you identify and document your managers', supervisors', and employees' support for the implementation of the quality system described in the QMP?		
1982			
1983			
1984			
1985	Q. Describe how you identify, define, and document the quality information needed to monitor the QMP's effective implementation?		
1986			
1987			
1988			

1989